

REDUCING RECIDIVISM IN ALASKA THROUGH ACCESS TO EXTENDED-RELEASE  
INJECTABLE NALTREXONE

by

Jyll K. Green, M.S.N.

A Dissertation Submitted in Partial Fulfillment of the Requirements  
for the Degree of

DOCTOR OF NURSING PRACTICE

in

Nursing

University of Alaska Anchorage

December 2016

APPROVED:

Lisa Jackson, D.N.P., Chair, Advisory Committee

Thomas Hendrix, Ph.D., Committee Member

Barbara Berner, Ed.D., Director

*School of Nursing*

William H. Hogan, M.S.W., Dean

*College of Health*

## **Abstract**

The goal of this evidence-based project was to provide access to extended-release injectable naltrexone (XR-NTX) upon release from incarceration for individuals who had a self-identified substance or alcohol abuse history, and evaluate whether or not XR-NTX reduced recidivism in comparison with those who declined to use XR-NTX. This project was completed in collaboration with Partners Reentry Center, located in Anchorage, Alaska, who collected and offered retrospective de-identified data for this project. A total of 98 individuals with a self-identified history of substance or alcohol abuse were offered XR-NTX through Partners Reentry Center from September 15, 2015 to September 15, 2016. Of these, 52 were offered XR-NTX in the first six months of this evidenced-based quality improvement project. Of those who accepted XR-NTX ( $n = 32$ ), 62% remained in the community at the end of 12 months from project initiation. Of those who declined XR-NTX ( $n = 20$ ), 95% recidivated. The results of this project demonstrate the benefit of using XR-NTX in released prisoners to reduce recidivism. Implications for use the of XR-NTX in Alaska Department of Corrections inmates and the general population who meet criteria for use should be evaluated.

*Keywords:* extended-release injectable naltrexone, recidivism

## Table of Contents

	Page
<b>Title Page .....</b>	<b>Error! Bookmark not defined.</b>
<b>Abstract.....</b>	<b>2</b>
<b>Table of Contents .....</b>	<b>3</b>
<b>List of Figures.....</b>	<b>8</b>
<b>List of Tables .....</b>	<b>9</b>
<b>List of Appendices.....</b>	<b>10</b>
<b>Chapter I: Overview of the Problem of Interest .....</b>	<b>11</b>
Background .....	12
Therapeutic courts and reentry program.....	13
Therapeutic courts in Alaska. ....	13
Reentry centers.....	14
Recidivism risk assessment. ....	14
Education and vocational assistance.....	15
Housing assistance.....	16
Substance abuse treatment.....	16
Behavioral health treatment and counseling. ....	17
Medication-assisted treatment. ....	17
Buprenorphine.....	18
Methadone.....	18
Acamprosate.....	18
Disulfiram.....	18
Naltrexone. ....	18
Clinical Significance .....	19
Current Clinical Practice .....	22
Question Guiding Inquiry.....	23

PICOT question. ....	23
Population (P). ....	23
Intervention (I). ....	23
Comparison (C). ....	24
Outcome (O). ....	24
Time (T). ....	24
Conclusion. ....	25
<b>Chapter II: Review of the Literature .....</b>	<b>26</b>
Methodology .....	26
Strategies .....	26
Data evaluation .....	26
Findings .....	27
XR-NTX post-release to reduce recidivism. ....	27
Length of treatment .....	28
Limitations .....	29
New studies for XR-NTX and prisoner reentry. ....	29
Conclusion. ....	31
<b>Chapter III: Organizational Framework .....</b>	<b>33</b>
Evidence-Based Practice Model. ....	34
Vision and mission .....	34
Goal. ....	34
Assumptions. ....	34
Inputs. ....	35
Activities. ....	35
Outputs. ....	35
Outcomes. ....	35
Impact. ....	35
Theoretical Framework .....	36
Education. ....	36

Persuasion.....	36
Incentivisation. ....	36
Training. ....	36
Environmental restructuring.....	37
Modelling.....	37
Enablement. ....	37
Conclusion.....	37
<b>Chapter IV: Project Design.....</b>	<b>38</b>
Institutional Review Board.....	38
Evidence-based practice. ....	39
Evidence-based quality improvement. ....	39
Clinical inquiry.....	39
Scientific and social value. ....	40
Scientific validity.....	40
Fair subject selection. ....	40
Independent review.....	41
Respect for potential and enrolled subjects. ....	41
Informed consent. ....	41
Evidence-Based Practice Change Design .....	42
Leadership. ....	42
Quality improvement team. ....	42
Materials and equipment. ....	43
Methodology and resources.....	43
Barriers to overcome .....	43
Community providers. ....	43
Time to administration.....	44
Cost and coverage of XR-NTX.....	44
Challenges of Collaboration.....	44
Plan for Project Evaluation .....	44
Data collection and analysis. ....	45

Post intervention plans.....	45
Conclusion.....	46
<b>Chapter V: Implementation Process and Procedures .....</b>	<b>48</b>
Project Implementation .....	48
Establishing relationships .....	48
Implementation of medication-assisted treatment (MAT) in the clinic setting .....	49
Screening for substance abuse history. ....	49
Screening for depression.....	51
Screening for the appropriate XR-NTX candidate .....	51
Administration of XR-NTX.....	52
Community outreach. ....	53
Incentivisation and environmental restructuring .....	53
Funding.....	53
Securing samples .....	54
Modeling and enablement .....	54
Barriers and Challenges to Implementation .....	55
Conclusion.....	56
<b>Chapter VI: Evaluation of Project Outcomes .....</b>	<b>57</b>
Outcome Measures .....	57
Data Analysis and Results .....	57
Additional measures to reduce recidivism.....	60
Discussion of Results .....	62
Limitations .....	62
Conclusion.....	63
<b>Chapter VII: Implications for Nursing Practice.....</b>	<b>64</b>
Essentials of Doctoral Education for Advanced Nursing Practice.....	64
Essential I: Scientific underpinnings for practice.....	64
Essential II: Organizational and systems leadership for quality improvement and systems thinking.....	65

Essential III: Clinical scholarship and analytical methods for evidence-based practice.....	65
Essential IV: Information systems/technology and patient care technology for the improvement and transformation of healthcare.....	66
Essential V: Health care policy and advocacy in healthcare.....	66
Essential VI: Interprofessional collaboration for improving patient and population health outcomes.....	67
Essential VII: Clinical prevention and population health for improving the nation's health.....	67
Essential VIII: Advanced nursing practice.....	67
Implications.....	68
Barriers to Implementation.....	69
Conclusion.....	71
<b>Chapter VIII: Summary and Conclusion.....</b>	<b>72</b>
Key Points.....	73
Conclusion.....	74
<b>References.....</b>	<b>75</b>
<b>Appendices.....</b>	<b>91</b>

**List of Figures**

Figure 6.1. Distribution of project participants by ethnicity.....	58
Figure 6.2. Distribution of project participants by age. ....	58
Figure 6.3. Recidivism rates at 12-months for participants enrolled during first six months.....	59
Figure 6.4. Comparison of Recidivism Rates Among Project Participants Who Accepted or Refused XR-NTX and Had Additional Support Measures.....	61
Figure 6.5. Comparison of Recidivism Rates Among Project Participants Who Accepted or Refused XR-NTX and Had No Additional Support Measures. ....	61



**List of Tables**

Table 5.1. Reimbursement for SBIRT.....	50
Table 6.1. A Comparison of Recidivism Rates at 12-Months between Those Accepting and Refusing XR-NTX in First Six Months of Project Implementation.....	59

### List of Appendices

Appendix A. Logic Model .....	912
Appendix B. Logic Model Early Access Extended-Release Injectable Naltrexone .....	923
Appendix C. Behavioural Change Wheel .....	94
Appendix D. Partners for Progress Letter of Support.....	95
Appendix E. IRB Determination Letter .....	96
Appendix F. XR-NTX Patient Counseling Checklist .....	100
Appendix G. NIDA Quick Screen V1.0/ NIDA-Modified ASSIST V2.0.....	10405
Appendix H. Patient Health Questionnaire 9.....	11415
Appendix I. Medication-Assisted Treatment of Opioid Use Disorder: Pocket Guide .....	11617
Appendix J. Clinical Opiate Withdrawal Scale .....	12424
Appendix K. Clinical Institute Withdrawal Assessment of Alcohol Scale-Revised .....	<b>Error!</b>

**Bookmark not defined.25**

## Reducing Recidivism in Alaska through Access to Extended-Release Injectable Naltrexone

### **Chapter I: Overview of the Problem of Interest**

Nationwide, approximately 65% of individuals incarcerated in the criminal justice system are clinically addicted to drugs or alcohol. Another 20% admit that drugs or alcohol were involved at the time of their crime (National Center on Addiction and Substance Abuse at Columbia University [CASA], 2010). Alaska communities are suffering the consequences of crimes related to drugs and alcohol. Of 25,385 crime victims in Alaska in 2010, 7,996 were attributed to drug or alcohol use (McDowell Group, Inc., 2012). An estimated 37.1% of women in Alaska will be victims of sexual violence, of which 72.2% are a result of drug or alcohol use (Alaska State Troopers' Alaska Bureau of Investigation Statewide Drug Enforcement Unit [SDEU], 2014). According to the 2014 Annual Drug Report published by the SDEU, marijuana remains the number one reason for arrests directly related to drugs or alcohol (49%), followed by methamphetamines (16%), heroin (14%), alcohol (12%), prescription drugs (7%), and cocaine (2%). Of particular concern, heroin addiction has doubled in the past decade and is now deemed an epidemic by the Centers for Disease Control and Prevention (CDC) (2015a).

According to a 2012 report on the economic effects of drugs and alcohol in Alaska, in 2010 there were 35,386 total arrests made, with 18,296 (52%) related to substance abuse. Of these 18,296 arrestees, 1,529 were incarcerated at the cost of \$56.7 million (McDowell Group, Inc., 2012). Alaska ranks in the top 10 states in the nation for illicit drug or alcohol abuse, where 13.3% of adults admitted illegal drug use in the prior month in comparison to the national average of 9.28% (SDEU, 2014). Higher rates of substance abuse will lead to higher crime rates (National Institutes of Health [NIH], 2013). Incarceration presents an opportunity to become free of drugs or alcohol. However, many prisoners release from incarceration and return to

substance abuse. A 2014 Bureau of Justice Statistics report found that 76.9% of drug offenders released in 2005 returned to prison by 2010 (Durose, Cooper, & Snyder, 2014); the greatest recidivism rate occurs within the first year after release (Gutierrez, 2015).

The Alaska Department of Correction (ADOC) facilities are currently operating at 101% of capacity. An 11% increase in incarcerated criminals is expected by 2018, primarily related to drug or alcohol abuse (Gutierrez, 2015). It is clear that to reduce drug and alcohol related crime, recidivism, and the economic impact to the State of Alaska, efforts should focus on evaluation and treatment of substance misuse within the ADOC and as prisoners are released back into the community.

## **Background**

Criminal recidivism is defined as the return to the criminal activity that results in rearrests, additional sanctions, or repeat incarceration (National Institute of Justice [NIJ], 2014). Recidivism can be viewed either as a failure of the individual for not rehabilitating themselves and choosing to be a good citizen or seen as a failure of the corrections system (Telidevara, 2010). The Alaska Judicial Council conducted a study in 2007 looking at recidivism rates for 1,798 individuals who were sentenced during the year 1999 and found that 66% had recidivated within three years of release. Further, recidivism within three years decreased to 63% in 2011 when reformative programs were reinstated within the ADOC. However, Alaska's incarcerated population has continued to rise by 3% annually with projections as high as 12% over capacity by 2018 (Gutierrez, 2015). Change is necessary to reduce recidivism and decrease the ADOC prisoner population.

The 2015 Alaska Recidivism Reduction Plan (Gutierrez, 2015) is an evidence-based plan focusing on the most efficient ways to reduce recidivism. Initiatives recommended by this plan

include collaboration within the Alaska therapeutic courts and community reentry partners, education and vocation programs, mental health treatment, housing needs, and substance abuse treatment. There has been considerable community involvement throughout Alaska focusing on several of these initiatives.

**Therapeutic courts and reentry program.** Therapeutic courts are problem-solving courts comprised of a team of judicial staff working to ensure the future success of the defendant via behavioral health and substance abuse treatment in conjunction with careful monitoring by probation officers or guardians (Alaska Court System, n.d.; National Association of Drug Court Professionals [NADCP], n.d.). The first therapeutic court was a drug court developed in 1989 in Miami-Dade, Florida. As of 2012, there was a total of 2,734 drug courts throughout every state nationwide (NADCP, n.d.).

***Therapeutic courts in Alaska.*** Therapeutic courts within the Alaska Court System have been in operation since 1999. In Alaska, there are 12 therapeutic courts comprised of wellness (substance abuse) and mental health courts, as well as several specialty therapeutic courts in Anchorage such as the Alaska for Veterans and Child in Need of Aid courts (Alaska Court System, n.d.; Gutierrez, 2015). Participation in the therapeutic court system is voluntary; the defendant must plead guilty to the charges, and must have a diagnosed substance abuse and/or mental health disorder. Participation is in lieu of jail time. However, failure to complete the program results in usual sentencing for the crime (Alaska Court System, n.d.). A 2012 report by the Alaska Judicial Council examined recidivism rates for 322 of over 500 Alaska Therapeutic Courts participants since the therapeutic courts' inception in 1999. A comparison of misdemeanants who graduated from the therapeutic court program with those who did not participate in a therapeutic court program identified a rearrest rate of 23% versus 36% and a

reconviction rate of 9% versus 25% within one-year post-release. A comparison of felons who graduated from the therapeutic court program and felons who did not attend a therapeutic court program found a rearrests rate of 25% versus 36% and a reconviction rate of 12% versus 23% within one-year post-release (Alaska Judicial Council, 2012). Given these outcomes, there is evidence that the therapeutic court system in Alaska is effective at reducing recidivism.

***Reentry centers.*** For substance abuse treatment to be beneficial, the treatment should be comprehensive and address all the needs of the individual including medical care, legal services, behavioral health services, social services such as food or housing needs, and vocational needs (National Institute on Drug Abuse [NIDA], 2012a). Reentry Centers focus on identifying needs and providing resources for recently released prisoners and work with parole officers and the community to promote community success. There are Reentry Centers located in Anchorage, Juneau, Matanuska-Susitna Valley, Fairbanks, and Dillingham (Gutierrez, 2015). Partners Reentry Center (PRC) in Anchorage, Alaska, is a non-profit organization founded in 2013 with a goal to reduce recidivism by providing comprehensive services for recently released prisoners who are classified as high risk (Boots, 2013; Partners Reentry Center, n.d.). PRC looks at the individual and assesses their basic needs for living as well as focusing on substance abuse disorders.

***Recidivism risk assessment.*** Recently released prisoners need a multifactorial approach to reducing the risk of recidivism and have successful reentry into their community. Of those incarcerated today, 95% will be released at some point in time (James, 2015), with varying needs to successfully reenter their community. The Level of Supervision Inventory-Revised (LSI-R) assessment is a 54 question quantitative tool to determine offender risk and best practices for intervention and treatment that improve post-release outcomes (Andrews & Bonta, 1995).

Labrecque, Smith, Lovins, and Latessa (2014) studied the theoretical benefit of using the LSI-R to predict risk of recidivism at initial screening and post interventions and found there was a positive correlation between LSI-R score and recidivism risk at both initial and subsequent scoring ( $r = .20$  and  $.23$ , respectively,  $p < .01$ ). The level of services provided post release from incarceration need to correlate with LSI-R score. A person with a high LSI-R score needs more services than a person with a low LSI-R score. It is important to note that if an individual with a high LSI-R score is provided with a low level of services, and conversely if an individual with a low LSI-R score is provided with a high level of services (effectively mixing both high and low risk individuals), then recidivism increases (Marlowe, Festinger, Lee, Dugosh, & Benasutti, 2006). Thus, it is important to match the level of services based on actual risk and needs.

**Education and vocational assistance.** Those convicted of a felony or misdemeanor in the State of Alaska have significant trouble gaining employment. In Alaska, an estimated 51% of the adult working population has a conviction that may limit their ability to obtain employment (Gutierrez, 2015). The Washington State Institute for Public Policy report showed that community-based education/training programs for employment had a 99% chance of having the financial benefit of the program outweighing the cost (\$5949 versus \$138) (Aos & Drake, 2013). However, Visser, Wintershield, and Coggeshall (2005) conducted a small meta-analysis of 33 ex-offender employment programs and did not find statistically improved recidivism rates. Alaska has already established job resources for released prisoners. As of January 1, 2015, within their first 16 months of operation, PRC assisted 1,096 individuals with job training or employment readiness services. Additionally, the Alaska Department of Labor and Workforce Development have many programs and community collaborations in place to help prisoners gain employment upon release (Gutierrez, 2015).

**Housing assistance.** Having a place to live is a basic social need. Approximately 48% of study participants (roughly 30% of ADOC prisoner and probation population) reported being homeless at least one time before incarceration. There are many barriers to receiving housing in Alaska including landlord restriction on renting to those with a prior criminal record, federal and state restrictions on renting subsidized housing to those with a prior criminal record, and a high cost of rent (Gutierrez, 2015).

**Substance abuse treatment.** Drug or alcohol use is often the reason for recidivating (Durose et al., 2014). Phillips (2010) conducted a qualitative study of 20 prisoners who had at least one prior incarceration. Fifteen of the 20 interviewed identified substance abuse as the cause of recidivating. The remaining five admitted to using substances upon release, although the primary reason for recidivating was not substance abuse. ADOC estimates 80% of inmates have a history of abusing drugs or alcohol (Gutierrez, 2015). The 2015 National Drug Control Strategy (Office of National Drug Control Policy, 2015) points out that substance misuse is a medical disorder that is preventable and treatable, much like any other illness. This 2015 Strategy was created to reduce substance abuse in the United States by creation of the following goals as stated by President Obama:

- Preventing drug use in our communities;
- seeking early intervention opportunities in health care;
- integrating treatment for substance use disorders into health care and supporting recovery;
- breaking the cycle of drug use, crime, and incarceration;
- disrupting domestic drug trafficking and production;
- strengthening international partnerships; and



improving information systems to better address drug use and its consequences. President Obama further delineated in this report that he would like to see budgeted funds of \$133 million go towards state-level prescription drug overdose prevention, access to the opioid reversal agent naloxone, and Medication-Assisted Treatment (MAT) programs (Office of National Drug Control Policy, 2015).

***Behavioral health treatment and counseling.*** Behavioral health treatment and counseling is necessary for success in drug and alcohol treatment. In fact, federal law mandates concurrent behavioral health interventions when treatment includes opioid replacement therapy for substance abuse (Substance Abuse and Mental Health Services Administration [SAMHSA], 2015b). Approximately six out of ten individuals who abuse drugs or alcohol also have a mental illness, thus necessitating concurrent treatment of counseling along with consideration for MAT (NIDA, 2012a). Additionally, an estimated 65% of ADOC inmates are beneficiaries of the Alaska Mental Health Trust Authority (ADOC, 2014). Approximately 30% of ADOC inmates have coexisting mental health and substance abuse diagnoses (Gutierrez, 2015).

***Medication-assisted treatment.*** NIDA (2012a) recommends pharmacotherapy as part of substance abuse treatment. They further recommend that treatment should be immediately available to prevent loss of the opportunity to treat. Knudsen, Abraham, and Roman (2011) conducted interviews with 345 private substance abuse treatment programs and found that MAT was utilized in only 24% of alcohol-dependent patients and 34% of opioid-dependent patients. At present, there are three medications used in MAT for opioid dependency: buprenorphine, methadone, and naltrexone. Naltrexone is available either orally or via an injectable extended-release naltrexone (XR-NTX). For alcohol-dependent individuals, the medications used for MAT are naltrexone, acamprosate, and disulfiram (SAMHSA, 2015b).

*Buprenorphine.* Buprenorphine is an oral medication available in several formulations such as a pill or film. It is a partial opioid agonist which can reduce withdrawal symptoms from opioids but can also cause euphoria and respiratory depression. Buprenorphine requires monthly visits to a licensed medical doctor who is certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) to prescribe this medication. The Federal Drug Administration (FDA) states that buprenorphine is to be used indefinitely (SAMHSA, 2015b).

*Methadone.* Methadone is a synthetic opioid that helps reduce withdrawal from heroin or other opioids and requires monthly visits to an SAMHSA certified outpatient treatment program for dispensing. It is a maintenance medication, meant to be used long-term (Office of National Drug Control Policy, 2012; SAMHSA, 2015b). Methadone carries a risk of diversion and abuse, and there is great concern over the possibility of overdose with methadone if drug dosing is not carefully monitored (Oser, Knudsen, Staton-Tindall, Taxman, & Leukefeld, 2009).

*Acamprosate.* Acamprosate is used as a maintenance medication for alcohol dependency. It is started on day five of sobriety and is taken orally three times a day for an indefinite basis to reduce the desire to consume alcohol. It does not assist with withdrawal symptoms and can be continued despite relapse in sobriety (SAMHSA, 2015b).

*Disulfiram.* Another medication used for chronic alcohol dependence is disulfiram, which is started a minimum of 12 hours after last alcohol intake. It works by changing the breakdown of alcohol to form acetaldehyde. Disulfiram will cause nausea and vomiting if taken while alcohol is consumed (NIDA, 2009; SAMHSA, 2015b).

*Naltrexone.* Extended-release injectable naltrexone (XR-NTX), brand name Vivitrol, manufactured by Alkermes, is an opioid antagonist indicated for use in recovery from opioid or alcohol dependency. The FDA first approved XR-NTX for the treatment of alcohol dependence

in 2006 and opioid dependence in 2010 (Drugs.com, 2015). When using XR-NTX for the treatment of alcohol abuse, it blocks the reward and intoxication from consuming alcohol (SAMHSA, 2015b). It is not a controlled substance or addictive, has no withdrawal, and may be prescribed by any primary care provider for eligible patients. XR-NTX is given via intramuscular injection at a dose of 380 mg every four weeks. Those who are opioid-dependent need to be opioid-free for at least seven days before initiation of XR-NTX to prevent rapid withdrawal (Alkermes, 2013b; Office of National Drug Control Policy, 2012; SAMHSA, 2015b). Clinical trials for XR-NTX researched use up to six months for opioid or alcohol abuse, although it can be used indefinitely for those with intense cravings (Alkermes, 2013b).

### **Clinical Significance**

MAT can be utilized to meet the 2015 National Drug Control Strategy goal of “breaking the cycle of drug use, crime, and incarceration” (Office of National Drug Control Policy, 2015). Although pharmacological treatment of substance abuse is recommended, only half of all Drug Courts in the nation utilize MAT as part of their treatment plan (National Association of Drug Court Professionals, 2013). MAT is underutilized, mainly due to lack of knowledge regarding medication options and the benefit of their use in the treatment of addicts (National Association of Drug Court Professionals, 2013). There are approximately 21 states looking at utilizing XR-NTX in the criminal justice system (Alkermes, 2013a).

Aletraris, Edmond, and Roman (2015) evaluated data from 307 substance abuse treatment programs on the prevalence of using XR-NTX as part of their treatment program. They found that along with cognitive behavioral therapy, only 13% used XR-NTX for alcohol use disorder and 3% used XR-NTX for opioid use disorder. The availability of wraparound services (medical and behavioral health care, housing, and transportation services), insurance

coverage, and availability of inpatient detoxification contributed to the positive use of XR-NTX. Cost, lack of knowledge, and a lack of an inpatient rehabilitation centers were cited as negatives regarding the use of XR-NTX.

A study in Missouri conducted by Crits-Christoph, Lundy, Stringer, Gallop, and Gastfriend (2015) looked at 2882 released offenders with a history of alcohol or opioid abuse history who were in treatment for substance abuse. They compared various agents used for MAT including XR-NTX, oral naltrexone, and buprenorphine/naloxone. Of the 2882 participants: 156 received XR-NTX, 45 received oral naltrexone, 168 received buprenorphine/naloxone, and 2513 received psychotherapy only. At admission to treatment, 45.4% were free of alcohol or drug abuse. The percentage of improvement in abstinence at discharge from treatment was 66.9% for XR-NTX, 23.2% for oral naltrexone, 22.2% for buprenorphine/naloxone, and 17.9% for only psychotherapy. Those treated with XR-NTX were more likely to achieve abstinence in comparison to all other treatment groups: oral naltrexone ( $p = .018$ ), buprenorphine/naloxone ( $p < .0001$ ), and psychotherapy only ( $p = .003$ ). Moreover, they found that treatment retention time was significantly higher for XR-NTX, 95 days, versus oral naltrexone 59 days ( $p = .025$ ) and psychotherapy only 85 days ( $p = .0005$ ). Treatment retention time in comparison to buprenorphine/naloxone was not significant ( $p = .096$ ).

Nationwide, MAT is underutilized (Aletraris, 2015; National Association of Drug Court Professionals, 2013). ADOC utilizes MAT in their treatment plans while incarcerated and after release through the therapeutic courts, but they lack sufficient funding to provide for all of those in need (Gutierrez, 2015). Only 10 percent of released inmates in Alaska gain access to supervised community-based substance abuse treatment after release—approximately 500 of 5,000 that are candidates for treatment (Martin & Colt, 2009). ADOC can currently treat only

468 individuals per year in community-based substance abuse treatment programs (Gutierrez, 2015). A study conducted by the Institute of Social and Economic Research at the University of Alaska Anchorage evaluated the economic impact of adding services within the ADOC to reduce criminal recidivism in Alaska (Martin & Colt, 2009). They determined that spending \$4 million annually from 2009 through 2030 (\$124 million accounting for inflation) would save the State \$321 million in costs otherwise dedicated to housing and construction of a new prison facility. Education/Vocation training and outpatient substance abuse programs save two to four times the expense of the program and reduce recidivism by four percent. Residential substance abuse treatment, therapeutic courts, and mental health care when transitioning from prison save two to seven times the cost of implementation and reduce recidivism by four to 11 percent (Martin & Colt, 2009).

Many view the prescribing of buprenorphine and methadone for addiction recovery as substituting one addictive substance for another (Oser et al., 2009; SAMHSA, 2015b). Nationwide, there is a trend toward using XR-NTX, instead of opioid replacement therapy, to treat opioid dependence. XR-NTX is desirable because of patient preference to remain opioid-free, its extended-release preparation that increases adherence, and the lack of withdrawal symptoms if a dose is missed (SAMHSA, 2012). According to a private conversation with Michael Eldridge, Addiction Recovery Associate, Alkermes, on September 29, 2015, XR-NTX has been underutilized in the State of Alaska, in part, due to lack of access.

There is no single evidence-based approach for the treatment of substance abuse. Several studies have evaluated and proven the efficacy of XR-NTX in reducing recidivism. Although naltrexone is supported by evidence to significantly reduce alcohol and opioid misuse for released prisoners (Crits-Christoph et al., 2015; Coviello et al., 2012), XR-NTX is underutilized

in the treatment of alcohol and opioid use disorders. There are many barriers to overcome in order to increase use of XR-NTX as part of a formal substance abuse treatment program. However, more data is needed to facilitate broad reaching adoption by states as they decide to utilize XR-NTX in the corrections system to reduce recidivism.

### **Current Clinical Practice**

In Anchorage, recently released prisoners have difficulty accessing MAT. Barriers to initiating MAT in the recently released prisoners are multifactorial. Being uninsured or underinsured limits the availability and affordability of medical care needed to receive MAT (Gutierrez, 2015). The recent Medicaid expansion in Alaska allows more people access healthcare (State of Alaska, 2015b). However, there is limited availability of providers willing to see Medicaid recipients (The Foundation for Government Accountability, 2013). Even the Federally Qualified Health Center in Anchorage, Alaska has a one-year backlog of patients waiting for appointments (Hanlon, 2015). One of the goals of Medicaid expansion in Alaska was to reduce recidivism by providing access to behavioral health care and medical treatment for substance abuse (Gutierrez, 2015). Healthcare providers, both medical and behavioral, need to take assignment of patients with Medicaid benefits to meet this goal.

Prisoners leaving the ADOC are screened and assigned a risk score for recidivating. The high-risk population released from incarceration in Alaska is referred to Partners Reentry Center (PRC) for consultation and wrap around services to help with successful reentry into their community. High-risk individuals are those who lack resources and would likely be otherwise homeless upon release from incarceration, placing them at a higher probability of recidivating (Council of State Governments, 2015). PRC has committed to providing substance abuse counseling for their clients via Moral Reconation Therapy (MRT) (Partners for Progress, n.d.).

There is heightened interest in getting released prisoners to choose XR-NTX to aid in the path to alcohol or substance abuse recovery. PRC reported difficulty gaining access to providers willing to screen and administer XR-NTX and have noted a three week waiting period, which significantly increases the risk of chronic substance abuse in the recently released (C. McLaughlin, personal conversation, November 3, 2015). Healthcare providers available for referrals with immediate availability are essential to the success of a recovery program utilizing XR-NTX.

### **Question Guiding Inquiry**

Every clinical inquiry begins with a problem and a proposed solution to improve the clinical process. PICOT (an acronym which stands for *population, intervention, comparison, outcome, and timeframe*) is one tool to guide inquiry of clinical practice and help define a succinct clinical question. A question developed using PICOT leads to clearly defined methods, design, and data analysis (Melnyk & Fineout-Overholt, 2015).

**PICOT question.** Will the development of a program aimed at providing early access to XR-NTX upon release from incarceration reduce recidivism rates in the State of Alaska?

***Population (P).*** The population for this study was recently released prisoners (typically day of release) from the Alaska Department of Corrections (ADOC) with a self-reported prior history of opioid or alcohol abuse who have been referred to PRC in Anchorage, Alaska.

***Intervention (I).*** The planned intervention was an initiative to facilitate day of release access to XR-NTX as a medical treatment for those individuals who desire MAT to aid substance abuse recovery. Released prisoners were educated regarding the availability, risks, and benefits of XR-NTX. Practices in Anchorage willing to screen and administer XR-NTX were trained to provide this medical treatment. A second intervention was collaborating with

PRC to facilitate access to Medicaid upon release from ADOC to improve access to healthcare. The pharmaceutical company Alkermes provided samples of XR-NTX for those awaiting medical insurance benefits through Alaska Medicaid or private insurance enrollment. Education was offered to interested parole and probation officers regarding the benefits and availability of XR-NTX, which helped facilitate the path of released prisoners to a medical provider who could provide this service.

**Comparison (C).** This project compared recidivism rates between those who voluntarily utilized XR-NTX and those who did not utilize XR-NTX. This data regarding the use of XR-NTX for recently released prisoners provided a rational foundation to create goals and expected long-term outcomes in regards to recidivism.

**Outcome (O).** The purpose of this project was to reduce recidivism in Alaska by improving access to XR-NTX to anyone who desired this medication as a tool to aid their recovery from substance abuse post-incarceration. There was not enough time to fully realize long-term recidivism reduction rates. Measuring recidivism rates over a six-month time frame was possible. A long-term goal, which was not likely to be achieved during the time frame of this project, was active ADOC involvement, preferably initiating the first injection of XR-NTX before release or “behind the wall” to minimize the risk of abusing a substance once a person is released back to their community.

**Time (T).** The time frame for this project was 12 months from initiation to completion, September 15, 2015, to September 15, 2016. Retrospective data from PRC was evaluated from this one-year time frame.



**Conclusion**

According to the 2015 Recidivism Reduction Plan (Gutierrez, 2015), recidivism rates in Alaska are high with approximately 63% recidivating within three years of release. Substance abuse is cited as the number one reason for recidivism in Alaska. Many who are released from prison lack even basic resources to integrate back into their community (Gutierrez, 2015).

Initiating a program to gain early access to MAT, specifically XR-NTX, along with behavioral health care, housing needs, and vocational assistance, may help reduce recidivism rates (Alaska Judicial Council, 2012; CASAColumbia, 2012 Gutierrez, 2015). A successful program for substance abuse would be proven by adherence to a plan including MAT, as well as showing an ongoing reduction in rates of recidivism and a decline in the ADOC prison population.

## Chapter II: Review of the Literature

As prison populations continue to rise in the United States, initiatives are being implemented to reduce recidivism. Medication-assisted treatment (MAT) is one part of the risk reduction for criminal recidivism. Criminal justice systems are interested in exploring treatment options for alcohol and substance abuse that do not involve opioid replacement therapy with buprenorphine or methadone (SAMHSA, 2012). Extended-release injectable naltrexone (XR-NTX) received approval as a pharmaceutical option for alcohol dependence in 2006. However, it is still a relatively new treatment for opioid addiction as it received Food and Drug Administration approval in 2010 (Drugs.com, 2015).

### Methodology

A comprehensive review of the literature was conducted to identify outcomes research using XR-NTX as part of substance abuse treatment in the released prisoner population.

**Strategies.** An online search for relevant literature was carried out by searching the following databases: CINAHL, Cochrane Library, PsycINFO, and Pubmed using keywords: naltrexone and criminal justice and prison. If no search results were found, keywords “injectable naltrexone” were used to avoid limiting the search results. Only articles published from 2010 through 2015 were included for current relevancy. The initial search yielded 32 articles in CINAHL under search term “injectable naltrexone,” 13 in Cochrane Library, 13 in PsycINFO, and 13 in Pubmed.

**Data evaluation.** The database searches were narrowed to include articles that pertained to use of XR-NTX in prisoner reentry, probation, parole, or the criminal justice system. Most of the studies found in the search focusing on outcomes of XR-NTX were small sample pilot

studies. No relevant articles were excluded for review due to the lack of abundance of articles for this population and intervention.

## **Findings**

The themes identified in existing research showed the relative newness of XR-NTX as an adjunct treatment for substance abuse. The use of XR-NTX to reduce recidivism rates has been explored and the length of treatment studied. Several articles reviewed the barriers to implementing a program that utilizes XR-NTX in the criminal justice system.

**XR-NTX post-release to reduce recidivism.** Finigan, Perkins, Zold-Kilbourn, Parks, and Stringer (2011) retrospectively reviewed data from two Michigan drug courts and one Missouri drug court for outcomes from implementing XR-NTX injections in addition to their standard treatment. They matched 32 high-risk individuals to a standard treatment group and 32 to a group using standard treatment with the addition of XR-NTX. The data was evaluated from June 2008 to December 2009, which was before the Federal Drug Administration approval in using XR-NTX for opioid dependency (Drugs.com, 2015). The relative risk reduction of 69% in annual recidivism rates for the standard group versus XR-NTX treatment group was statistically significant ( $p < .05$ ).

Lee et al. (2015b) conducted a small open-label, eight-week, proof of concept, non-blinded, pilot study to assess the primary endpoint of abstinence from opioids in released male prisoners at weeks 4 and 8 following randomization to the XR-NTX treatment group ( $N = 16$ ) vs the treatment as usual (TAU) group ( $N = 17$ ). One injection of XR-NTX was given before release and a second injection four weeks later. The primary endpoint of opioid relapse at week four was 38% for the XR-NTX group versus 88% in the TAU group, which was statistically

significant ( $p < .004$ ). Other secondary endpoints were not significant, including recidivism rates which were 13% in the XR-NTX group versus 44% in the TAU group ( $p < .03$ ).

Coviello et al. (2012) conducted a pilot study of 61 recently released offenders with a history of opioid dependency. They recruited individuals from five different sites for a voluntary MAT program using XR-NTX with branded Depotrex (approved by the FDA only for use in clinical studies). Of the participants, 72% were incarcerated for drug-related crimes. A baseline urine drug screen and a six-month follow-up urine drug screen were obtained, along with a self-reporting questionnaire. Forty percent of participants received six injections of XR-NTX, and 64% received three injections. Of the 74% of participants that completed the six-month follow-up, they found 15% of study completers had been re-incarcerated in comparison with 50% of non-completers, which was statistically significant ( $p = .011$ ). Half of the total participants were employed at the six-month follow-up. Although not statistically significant ( $p = .311$ ), completers of the study were more likely to be employed than non-completers (56 versus 39%).

**Length of treatment.** An open-label randomized controlled trial by Gordon et al. (2015) explored the relationship between the length of treatment with XR-NTX and criminal recidivism. Of the 27 study participants recruited while incarcerated, 10% completed seven monthly injections of XR-NTX, with the first injection administered before releasing from incarceration. Although not statistically significant ( $p = .123$ ), none of the 10% who completed six community injections of XR-NTX recidivated compared to 31.3% who completed less than six. A nine-month follow showed that none who completed seven injections total were opioid positive versus non-completers ( $p = .003$ ).

Lee et al. (2015a) conducted an 18-month, five sites, open-label randomized, controlled clinical trial that recruited 308 community-based individuals with prior criminal justice system

involvement to evaluate the primary endpoint which assessed the rate of being opioid-free at 27 weeks after six monthly XR-NTX injections. Of the 308, 153 were randomized to the XR-NTX group and 155 to the treatment as usual (TAU) group. The XR-NTX group retention was 74% for six months with an opioid relapse rate of 43% in the XR-NTX group versus 56% in the TAU group. Results from this study were reported as preliminary findings, with final results pending.

Lapham and McMillan (2011) conducted a small pilot study looking at the administration of XR-NTX for three months for offenders involved in the criminal justice system due to charges of driving under the influence. Eleven volunteers participated in this study, of which 10 received at least one injection of XR-NTX and seven received all three injections. Among all 11 participants, abstinence in alcohol increased by 31% from 56.8 to 82.0 alcohol-free days. The number of daily alcoholic drinks decreased by 77% from 3.0 to 0.7 which was statistically significant ( $p < .01$ ). The authors recognized that a large randomized controlled trial is needed to assess the validity of these findings.

### **Limitations**

There are few published studies regarding the use of XR-NTX in the criminal justice system or with the prisoner reentry population. The studies available utilized very small sample sizes and most were pilot studies. Although the mechanism of action for XR-NTX is different for alcohol addiction compared to an opioid addiction, studies for either population showed statistically significant efficacy of XR-NTX in significantly reducing recidivism and substance misuse. To gain validity and prove reproducibility, more published data is needed on the use of XR-NTX in the prisoner population.

**New studies for XR-NTX and prisoner reentry.** The ClinicalTrials.gov database was also searched in attempts to discover future studies using keywords naltrexone and prison.

Several trials in this database were found that aimed to evaluate the efficacy of XR-NTX and recidivism. The University of California, Los Angeles (2014) planned a study comparing individuals randomized to the use of XR-NTX, or XR-NTX with additional services of a patient navigator, or a drug education program without MAT, in order to assess the efficacy of treatments initiated prior to release from prison on community success and opioid relapse six months post release. The University of Oslo (2012) recruited inmates for a study that compared the success of XR-NTX versus buprenorphine-naloxone in post-release success at staying opioid-free at 12 weeks post release. The results are not available, but the study is closed. The University of Pennsylvania (2015) conducted research on 200 inmates randomized to pre and post release doses of XR-NTX to assess six-month outcomes pertaining to opioid relapse and recidivism rates with a goal of promoting initiating of XR-NTX before releasing from incarceration. Results are not yet available.

Rhode Island Hospital (2012) has completed a study assessing the use of XR-NTX pre and post release from incarceration and followed opioid relapse and recidivism rates at six, 12 and 18 months. Participants received six injections of XR-NTX and were randomized to receive their first injection before release from incarceration or to have all six injections in the community. Results of this study are unpublished.

New York University School of Medicine (2010) has completed a study comparing 30-day post-release opioid relapse rates of inmates who received XR-NTX before release from incarceration and a controlled group who received standard counseling. Results of this study are pending. New York University School of Medicine (2013) is recruiting for participants among jail inmates, and plans to randomize participants to post-release doses of XR-NTX and treatment as usual to assess time to opioid relapse over 24 weeks with secondary endpoints examining

recidivism rates, cost-effectiveness of treatments, and a planned comparison with a non-randomized jail-initiated methadone treatment group.

A NewsBank literature review to look for other new developments in the use of XR-NTX in the prisoner population was conducted for years 2015 and 2016 using keywords naltrexone and prison. This search yielded 230 articles in the United States of America. The recent influx of news primarily speaks to the growing interest in using XR-NTX in the criminal justice realm as a means to reduce recidivism and improve health outcomes regarding substance abuse. Although not all of the articles reference published or ongoing research pertaining to XR-NTX, they do show there is an emerging nationwide effort towards achieving sobriety and reducing recidivism through the implementation of XR-NTX in addition to existing treatment programs.

## **Conclusion**

Recent research studies show there is a benefit to utilizing XR-NTX as part of a program for prisoner reentry aimed at reducing recidivism. However, there is limited published evidence on this topic, and most studies published evaluated small populations. XR-NTX offers a non-opioid replacement option for treatment of substance abuse. With the average cost of XR-NTX between \$800 and \$1200 per month, it is not surprising that cost is a barrier to providing this treatment for those with opioid or alcohol abuse histories (Alanis-Hirsch et al., 2015). A cost-analysis study showed the increased efficacy of XR-NTX over opioid agonist options, even though the cost for XR-NTX was significantly higher. The high upfront cost is likely a limiting factor for most criminal justice systems when treatment options are considered (Jackson, Mandell, Johnson, Chatterjee, & Vanness, 2015). Expansion of Medicaid in many states makes it easier to fiscally implement and sustain a treatment program that utilizes XR-NTX for alcohol and substance abuse treatment (Centers for Medicare & Medicaid Services, 2014). With Alaska

correctional facilities at 101% capacity (Gutierrez, 2015), it is prudent to explore options that reduce recidivism which include additional studies to analyze the long-term cost effectiveness of XR-NTX in the criminal justice setting.

The limitations in available research show that XR-NTX is an emerging treatment option that appears promising in early studies. There is a call to utilize evidence in efforts to reduce recidivism. Alcohol and opioid abuse treatment options using XR-NTX need to be further explored in the setting of prisoner reentry to see if this will significantly reduce recidivism rates and improve health outcomes over time.



### **Chapter III: Organizational Framework**

Healthcare providers have significant work to do in providing evidence-based care for substance abuse. A report from a five-year meta-analysis published by the National Center on Addiction and Substance Abuse at Columbia University (2012) showed that despite substance abuse being a diagnosable disease state, only one out of 10 substance-addicted individuals (excluding nicotine) receive any treatment, let alone treatment that is evidence-based.

Alaska Department of Corrections screens all of its inmates for substance abuse using the Simple Screening Instrument-Revised (SSI-R) assessment tool, however, they do not have the capacity to provide residential substance abuse treatment for the high volume of inmates for whom residential treatment is indicated. According to Gutierrez (2015), the fiscal year 2013 showed the capacity for residential treatment was 228 individuals when 793 individuals were identified as needing residential treatment according to the SSI-R. The outpatient substance abuse treatment capacity was adequate in 2013. Suggestions made by the Alaska 2015 Recidivism Reduction Plan recommend looking at policy changes that will provide residential treatment in conjunction with examining other measures to reduce recidivism (Gutierrez, 2015).

The Council of State Governments published the “Report of the Re-entry Policy Council” as the benchmark document for implementing initiatives and policy changes to benefit offender reentry (n.d.). Within this document, policy statement 32 addresses substance abuse treatment and policy statement 35 addresses improving health outcomes and reducing costs through improving access to quality care in the community upon release. Initiatives to move providers towards evidence-based practice are necessary for optimal outcomes in regards to substance abuse treatment, reduction in recidivism, and improved health.

### **Evidence-Based Practice Model**

A quality improvement (QI) initiative uses evidence to make changes in the healthcare system to improve patient care outcomes. There are many QI models that can be used as a systematic approach to guide change (Moran, Burson, & Conrad, 2014). The Council of State Governments recommends using a logic model to make it easy for stakeholders and policy makers to identify the participants and goals of an initiative involving prisoner reentry (n.d.). A logic model (Appendix A) is a simple visual model that can be used to plan, design, implement, and continually evaluate the implementation of a program and is often used to help program administrators and policymakers understand the full scope of the project. The model clearly identifies the process of implementation by showing **inputs** and **activities** that move towards arriving at the desired **outputs**, **outcomes**, and the **impact** made by implementation of the initiative. Various stakeholders contribute to different parts of the program, although there is a connection between all as detailed in the logic model. Logic models may utilize a theoretical approach to more clearly evaluate a process. This type of approach is often used when applying for funding as it incorporates the overall goal when looking at the implementation of one specific program (W.K. Kellogg Foundation, 2004). Inherent to using a logic model is to address **assumptions** that preempt the planned program implementation (Council of State Governments, n.d.). Appendix B shows the logic model and assumptions for the planned initiative to reduce recidivism by facilitating early access to extended-released injectable naltrexone (XR-NTX).

**Vision and mission.** Facilitate early access to XR-NTX for released prisoners, while educating healthcare providers about the use of XR-NTX to aid substance abuse treatment.

**Goal.** Reduce recidivism rate.

**Assumptions.** There are several assumptions for this project.

- Recidivism affects our community and partnerships formed within our community will help improve recidivism.
- Expanding Medicaid in the State of Alaska will improve access to care and substance abuse treatment.
- Shifting revenues to provide for early access to XR-NTX will improve health outcomes and reduce recidivism.
- Our community can unite to shape policy at local and state levels as it pertains to recidivism.

**Inputs.** Funding, Partners Reentry Center, clients, Alkermes and primary care providers all contribute to the effort of the initiative.

**Activities.** Create relationships with primary care providers who can see clients in a timely fashion, and are willing to screen and provide XR-NTX. Educate those involved with prisoners about XR-NTX. Secure sample medication and medication information from Alkermes.

**Outputs.** The number of sites administering XR-NTX and the number of offenders who chose to receive XR-NTX.

**Outcomes.** The percentage of offenders who accepted XR-NTX, the percentage of offenders who did not accept XR-NTX, the percentage of offenders who recidivated and accepted XR-NTX, and the percentage of offenders who recidivated and did not accept XR-NTX.

**Impact.** The effectiveness of the QI facilitating early access to XR-NTX and the reduction in recidivism can be measured using the retrospective data obtained from PRC.

## **Theoretical Framework**

Michie, van Stralen, and West (2011) created the Behaviour Change Wheel based on an analysis of 19 different behavioral health frameworks (Appendix C). They developed their model to look at the factors influencing behavior change and interventions that need to occur as the basis for creating changes in evidence-based practice and public health policy. The center of the model is the “COM-B” model, showing that capability and opportunity drive motivation and that all three are necessary to drive behavior change. There are nine interventions around the central behavior model, which can be used to drive change: education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modeling, and enablement. Several interventions in the Behaviour Change Wheel could be further defined to improve accessibility and use of XR-NTX in the recently released prisoner population.

**Education.** Education needs to occur to teach inmates about drug and alcohol abuse treatment and availability of XR-NTX. Primary care providers in the community need education on the use of MAT and XR-NTX for adjunct treatment for substance abuse.

**Persuasion.** Communicating benefits of XR-NTX and how the released prisoner's lives will change for the better could be viewed as positive persuasion.

**Incentivisation.** When used in the therapeutic court system, incentives could be considered by offering a lesser probation/parole period. For those who would be otherwise homeless, providing safe housing is motivation to stay clean and sober.

**Training.** Training primary care providers, substance abuse treatment centers, the department of corrections and the re-entry facilitators about the benefits and availability of XR-NTX will facilitate use.

**Environmental restructuring.** Environmental restructuring could remove physical or social barriers to enable immediate access to the healthcare system for those who require timely injection with XR-NTX before recurrent substance abuse occurs.

**Modelling.** Modeling would be used to look at existing data from corrections programs who have implemented the use of XR-NTX post release.

**Enablement.** Enablement could be used to obtain grant funding based on data obtained from implemented service programs aimed at reducing recidivism.

## **Conclusion**

A logic model was succinctly designed and was used to drive this QI initiative facilitating early access to XR-NTX for recently released prisoners. The model allows for ongoing evaluation and can be further used to evaluate if this initiative is cost beneficial to a larger system, like the Alaska Department of Corrections. The Behaviour Change Wheel model can be used to identify barriers to the use of XR-NTX to aid recovery from substance abuse.

Overcoming these barriers will help guide policy changes that are necessary to make XR-NTX more accessible to those recently released from incarceration who suffer from substance abuse.

## **Chapter IV: Project Design**

This project aimed to create early access to XR-NTX for recently released prisoners in Anchorage, Alaska and subsequently evaluated its effectiveness in reducing recidivism. Partners Reentry Center (PRC), a non-profit organization, agreed to collaborate for the purpose of this project (Appendix D). The aim was to create a succinct referral process for those who desire extended-release injectable naltrexone (XR-NTX) to aid in recovery from substance abuse with the goal to ultimately reduce recidivism in the State of Alaska. This initiative identified several barriers to overcome, mainly the lack of healthcare providers knowledgeable, willing, and able to provide timely access to XR-NTX. PRC collects data for each client they assist. Anonymous retrospective data was accessed one-year post implementation of this project to evaluate the impact of XR-NTX on recidivism in Alaska.

There are various types of projects that evaluate, implement and generate knowledge for clinical practice including evidence-based practice, evidence-based quality improvement, and clinical research (Melnik & Fineout-Overholt, 2015). Clinical inquiry involving human subjects needs to be reviewed by an Institutional Review Board (IRB) to ensure the protection of human subjects. An IRB application was made to the University of Alaska Anchorage IRB before implementation of this project.

### **Institutional Review Board**

The IRB at the University of Alaska Anchorage reviews project proposals to ensure the safety and well-being of research participants and a fair selection of study participants according to federal guidelines (University of Alaska Anchorage, 2012). There are three levels of IRB review including exempt, expedited, and full review. The U.S Department of Health and Human Services (HHS) discusses prisoner research in depth in 45 CFR part 46, subpart C (2009). The

extent of human subject involvement, type of project, and scope of outcomes reported determines the level of IRB review. Ethics and confidentiality are important conditions to consider when doing research regarding a vulnerable population (Gordon, Kinlock, & Miller, 2011). An IRB Determination Form was submitted for approval of this project. The UAA Compliance Officer determined this project did not involve human subjects and was exempted from IRB review (Appendix E).

**Evidence-based practice.** A project that focuses on evidence-based practice uses existing evidence and incorporates it into practice (Melnik & Fineout-Overholt, 2015). Although there is a body of research regarding XR-NTX, it is not yet highly utilized as a mainstream treatment for alcohol or opioid addiction, particularly within the State of Alaska. This project educated attendees at the September 2016 Alaska Nurse Practitioners Association conference about medication-assisted treatment (MAT) and XR-NTX, including its use in the prisoner population, with the goal of increasing access to substance abuse treatment within primary care.

**Evidence-based quality improvement.** While this project utilized evidence-based practice, the focus was on implementation strategies to improve access of XR-NTX to recently released ADOC population, and to evaluate the effectiveness of this strategy to reduce recidivism. Implementation strategies to improve clinical practice in regards to the use of XR-NTX in the medical treatment of alcohol or opioid addiction as an evidence-based treatment option were also developed. Given the small body of published knowledge on the use of XR-NTX in the prisoner population, this project will add to the evidence for the use of XR-NTX.

**Clinical inquiry.** Clinical inquiry and evidence-based quality improvement methods should give consideration to seven ethical principles including scientific and social value,

scientific validity, fair subject selection, favorable benefit compared to risk, independent review, respect for potential and enrolled subjects, and informed consent (Melnik & Fineout-Overholt, 2015).

**Scientific and social value.** Using XR-NTX to reduce recidivism and potentially reduce substance-related crime has clear social value. Sharing statistical outcomes relating the use of XR-NTX and recidivism rates will add to the body of science.

**Scientific validity.** Utilizing evidence-based medicine to implement a Quality Initiative will minimize risk to participants and should result in a rigorous project.

**Fair subject selection.** Participants in the project all volunteered to use XR-NTX thus avoiding the potential for coercion which is a basic tenant of human research subject protection.

**Favorable risk-benefit ratio.** Risks associated with XR-NTX include, but are not limited to any injection site reaction, hepatotoxicity, depression or suicidal ideation, allergic reaction, eosinophilic pneumonia, a risk of an opioid overdose after cessation of XR-NTX, or risk of opioid withdrawal with the initiation of XR-NTX (Alkermes, 2013c, 2015). Despite the risks listed in the product information, the discontinuation rate of XR-NTX versus placebo was 9% versus 7% for alcohol-dependent patients and 2% for both XR-NTX versus placebo in opioid-dependent patients (Alkermes, 2015). Clinical trial outcomes data using XR-NTX for alcohol-dependent patients showed significantly fewer heavy drinking days (defined as more than five daily drinks for males and four daily drinks for females) compared to placebo (Alkermes, 2015). Krupitsky et al. (2011) conducted a 24 week, randomized controlled trial on the efficacy of XR-NTX for opioid dependency on 250 participants. The group assigned to XR-NTX ( $N = 126$ ) had statistically significant higher median number of weeks of abstinence



compared to the placebo group ( $N = 124$ ), 90% versus 35% respectively (95% CI,  $p = .0002$ ). It would appear that the potential for benefits of receiving XR-NTX outweighs the risks.

XR-NTX is supported by evidence to significantly reduce alcohol and opioid misuse for released prisoners (Coviello et al., 2012; Crits-Christoph et al., 2015). The benefits of facilitating access to XR-NTX in a timely fashion may help reduce the risk of recidivism due to substance abuse while on probation. Subjects who seek a referral to a community medical provider for the purpose of receiving XR-NTX benefited from a medical screening, which may identify other health needs. Sample medication of XR-NTX may be utilized to begin treatment for those with no medical benefits.

**Independent review.** IRB review ensured ethical use of data regarding participants in this project.

**Respect for potential and enrolled subjects.** This project leader had no direct contact with participants and no ability to influence participation. XR-NTX treatment is a personal choice and is offered as an option for adjunctive treatment by PRC.

**Informed consent.** The U.S. Department of Health and Human Services OHRP publishes decision charts about human subject research to determine the level of IRB review and the requirement for participant consent (2004). Chart 10 explores the obligation to provide informed consent for participation in human subject research. XR-NTX was offered by PRC staff to appropriate clients presenting to PRC as an adjunct treatment in alcohol or opioid abuse recovery. The use of XR-NTX is not experimental and has documented evidence of statistically significant efficacy in the department of corrections population as noted in the review of the literature. Participant consent was not required as only de-identified data was ascertained from PRC from statistical data already collected on participants at PRC. Also, released prisoners

choose whether or not to utilize extended-release injectable naltrexone (XR-NTX) as part of their substance abuse treatment. A letter of support from Partners for Progress (Appendix D) was provided outlining their collaboration and willingness to provide de-identified data for the purpose of measuring the outcomes of this evidence-based practice initiative.

### **Evidence-Based Practice Change Design**

The logic model framing this project (Appendix B) offers a clear visualization of the initiative and the expected short and long term outcomes that were reported. The primary stakeholders in this initiative can easily identify where their participation is imperative. The expected outcomes and community impact of this evidence-based implementation project are also easily visualized.

**Leadership.** A quality improvement initiative will only be successful with the right people influencing and moving towards change. Initiating early access to XR-NTX required healthcare providers willing to screen and utilize medically assisted treatment to aid in the treatment of alcohol or opioid abuse. With the assistance of PRC and other existing and new community partners, this project intended to reduce barriers and create solutions to implementing early access to XR-NTX with a long-term goal to reduce recidivism. This initiative also sought to drive funding and policy change to further efforts towards access to XR-NTX.

**Quality improvement team.** PRC, probation and parole officers, judicial employees, and community healthcare providers were all involved in this quality improvement initiative. Partners for Progress holds bimonthly meetings with the principle stakeholders with the goal to reduce recidivism and improve prisoner success at community reentry in the State of Alaska. These meetings provided a forum to discuss all matters about recidivism and prisoner reentry.

**Materials and equipment.** Patient education on XR-NTX was made available to PRC, healthcare providers, and anyone else in direct contact with participants interested in receiving XR-NTX (Appendix F).

**Methodology and resources.** An initial meeting at Partners Reentry Center on September 15, 2015, with the Director of Partners Reentry Center and the Chair of the Board for Partners for Progress identified the desire to implement an initiative to gain access to XR-NTX as part of substance abuse treatment for high-risk recently released prisoners. Limited grant funds were available to provide screening and administration of XR-NTX if sample medication was available. Anonymous data was provided by PRC to evaluate the success of the initiative using XR-NTX to reduce recidivism.

**Barriers to overcome.** PRC identified several existing barriers to implementing this initiative. Currently, there is a lack of community providers willing or knowledgeable enough to administer XR-NTX. Another barrier identified was the amount of time until an appointment to administer XR-NTX, which increased the risk for substance abuse in time frame between release and injection with XR-NTX. The cost of XR-NTX and lack of insurance coverage were also identified as a significant barrier to providing adjunct treatment with XR-NTX. For this initiative to move forward, plans to overcome identified barriers to implementation were addressed.

**Community providers.** Provider willingness to be a referral source for the administration of XR-NTX is a critical piece of this initiative. Alkermes utilizes an Anchorage-based Addiction Recovery Specialist to educate healthcare providers across the state (including behavioral health, substance abuse programs, and primary care providers). Education is the fundamental component of facilitating awareness and efficacy regarding XR-NTX.

***Time to administration.*** Providers and their support staff willing to be a referral source for the administration of XR-NTX were educated on the need for timely administration of XR-NTX post-release.

***Cost and coverage of XR-NTX.*** If participants did not have medical benefits, they were assisted by personnel at PRC in applying for Alaska State Medicaid which would help fund ongoing treatment. Alkermes was generous in providing XR-NTX samples to providers willing to facilitate early access post prisoner release for uninsured or underinsured individuals who desired treatment with XR-NTX. Alkermes has historically funded “first shot behind the wall” programs if the department of corrections is willing to adopt this policy for interested prisoners (Beck, 2015), and they have expressed willingness to provide samples to the ADOC.

### **Challenges of Collaboration**

High-risk prisoners reentering their community require reliable resources to facilitate their success. Anticipated barriers in this initiative to facilitate early access to XR-NTX for recently released prisoners were considered. These included waning interest in the initiative as time progresses, lack of provider willingness to become educated regarding XR-NTX, increased demand on the few facilities who are willing to provide XR-NTX causing delay in initiating XR-NTX, funding availability for XR-NTX screening and administration, lack of timely access to Alaska State Medicaid or other insurance coverage post-release, reduced availability of XR-NTX sample medication that will facilitate early access regardless of insurance benefits, and perceived high risk/ low benefit by released prisoner in regards to use of XR-NTX.

### **Plan for Project Evaluation**

Process improvement and policy needs to be directed at appropriate treatment of addiction to drugs or alcohol as a means to reduce recidivism. Many released from prison lack

access to recovery resources for substance abuse. Initiating a program to facilitate early access to counseling and XR-NTX for those recently released from incarceration may help reduce recidivism rates. The outcomes measured to evaluate the effect of XR-NTX on recidivism could support policy change if outcomes were significant.

**Data collection and analysis.** PRC serves clients that voluntarily present for community reentry assistance upon release from incarceration. These clients either self-refer or are referred by the Alaska Department of Corrections based on Level of Service Inventory-Revised screening conducted before release. Data is collected on all clients served through PRC. Demographic data is collected including gender, race, and age. PRC also receives extensive information about the criminal history and social history including substance abuse history. Clients with a history of alcohol or opioid abuse are educated regarding and offered access to XR-NTX as part of a comprehensive treatment program along with Moral Reconation Therapy (MRT). Client participation in treatment with XR-NTX is not tied to probation or utilized as a bargaining tool for receipt of other services. PRC tracks data on their clients in regards to alcohol or opioid abuse history, whether or not the client was offered and received XR-NTX as part of a treatment program, and recidivism. PRC prepares quarterly reports that offer de-identified data. Outcomes data reported for this project include numbers served, use and declination of XR-NTX, recidivism rates for those who opted to use XR-NTX, and recidivism rates for those who did not utilize XR-NTX.

**Post intervention plans.** After obtaining outcomes data, the information was presented to the ADOC for consideration regarding the utilization of XR-NTX as an adjunct to reduce recidivism and treat substance abuse. This project may motivate government officials to initiate changes in policy with regards to parole to include an emphasis on the use of XR-NTX instead of

opioid replacement therapies, with consideration for the first injection of XR-NTX given before release from the DOC to minimize risk for substance misuse and subsequent recidivism after release from incarceration. The outcomes of this project should convince ADOC that adequate resources exist to continue the adjunctive treatment of prisoners upon release to communities across the state. The findings generated by this project will hopefully be beneficial to ascertain future funding for PRC.

## **Conclusion**

XR-NTX is an effective tool in reducing rates of recidivism in those with a prior history of alcohol or opioid use. A small number of studies throughout the United States have shown promising data when utilized in prisoner populations. One barrier to using XR-NTX in the Anchorage community was a lack of primary care providers who have received education on substance abuse and use of XR-NTX, as well as having sites available for immediate screening and administration of XR-NTX. A delay in screening and care may result in recurrence in substance misuse and subsequent recidivism, so timing is critical to the success of this program. This project found healthcare providers willing to provide XR-NTX and receive knowledge of MAT and the use of XR-NTX. Another barrier to utilization of XR-NTX is cost. Expansion of Alaska Medicaid eligibility increased access to substance abuse treatment; many qualify for Medicaid benefits upon release from incarceration. Enrolling individuals in Alaska Medicaid would alleviate a financial barrier to obtaining XR-NTX. Samples have historically been provided by Alkermes to facilitate early access to XR-NTX, but, for program sustainability, insurance coverage is required. PRC greatly assisted in the implementation of this XR-NTX access initiative. This project provided early data on recidivism rates for released prisoners who

choose to use XR-NTX as an adjunct to other services provided by PRC. The State of Alaska should appreciate the continued decline in recidivism rates for those former inmates who participate in substance abuse treatment.

## **Chapter V: Implementation Process and Procedures**

This project utilized a logic model to guide implementation of providing access to extended-release injectable naltrexone (XR-NTX) for recently released prisoners (Appendix B). Having a clear set of activities needed for project implementation increases the chance of successful outcomes (W.K. Kellogg Foundation, 2004). The activities listed in the logic model for this project generated data that was critical for gauging its success. Also, the Behaviour Change Wheel (Appendix C) (Michie, van Stralen, & West, 2011) was utilized to guide interventions that needed to occur to support integrating evidence-based practice and public health policy.

### **Project Implementation**

The logic model provided a visual model to help all stakeholders involved in the implementation of this project. The model provided four clear steps or activities that needed to be accomplished to show the success of this project. The expected outcomes and impact to the community were also anticipated.

**Establishing relationships.** The first step or activity was building relationships with local providers involved in substance abuse treatment. Through networking with the assistance of Michael Eldridge, Addiction Recovery Associate from Alkermes pharmaceutical company, primary care providers were identified in the community who would be interested in administering XR-NTX. Local substance abuse treatment programs were also approached regarding the potential benefits of XR-NTX during recovery. This step was largely implemented through phone consultations and in-person discussions with interested providers and healthcare organizations which included lengthy deliberations on the importance of early access to XR-NTX upon release from incarceration and the importance of timely follow-up injections.



**Implementation of medication-assisted treatment (MAT) in the clinic setting.**

Although XR-NTX has had FDA approval since 2006 for alcohol dependency and 2010 for opioid dependence (Drugs.com, 2015), medication-assisted treatment (MAT) is still vastly underutilized likely due to a lack of knowledge regarding medication use and benefits (National Association of Drug Court Professionals, 2013). Primary care providers are in a prime role for screening and initiation of treatment for those with a history of substance abuse. For this project, many providers needed comprehensive education regarding the use of XR-NTX.

***Screening for substance abuse history.*** The Substance Abuse and Mental Health Services Administration (SAMHSA) developed the Screening, Brief Intervention, and Referral to Treatment (SBIRT) program as an evidence-based model for detecting substance abuse risk (2016b). The first step in SBIRT is to identify those at risk of substance misuse. It is recommended that healthcare providers initially ask all patients “How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons?” (Smith, Schmidt, Allensworth-Davies, & Saitz, 2009). The National Institute on Drug Abuse (NIDA) modified this question and created the NIDA Quick Screen Question (Appendix G) to screen for alcohol and tobacco use successfully (2012b). Any positive response to the NIDA Quick Screen question should prompt additional screening. If the patient answers yes to more than one day of heavy drinking, NIDA recommends that the healthcare provider reviews the publication “How to Help Patients Who Drink Too Much: A Clinical Approach” (NIDA, 2005). NIDA recommends using the NIDA-Modified ASSIST if the patient states they used illegal or prescription drugs for nonmedical reasons (Appendix G) (2012b). An available online version of the NIDA-Modified ASSIST tool with automatic scoring, risk assessment, and appropriate recommendations for follow-up is available at <https://www.drugabuse.gov/nmassist>. It is also

possible to link this screening tool directly to a healthcare provider electronic health record (NIDA, 2012b). Healthcare providers can code for reimbursement for conducting SBIRT screening if an intervention is required; otherwise, the office visit charge includes the screening:

Table 5.1

*Reimbursement for SBIRT***Reimbursement for SBIRT**

<b>Payer</b>	<b>Code</b>	<b>Description</b>	<b>Fee Schedule</b>
<b>Commercial Insurance</b>	CPT 99408	Alcohol and/or substance abuse structured screening and brief intervention services; 15 to 30 minutes	\$33.41
	CPT 99409	Alcohol and/or substance abuse structured screening and brief intervention services; greater than 30 minutes	\$65.51
<b>Medicare</b>	G0396	Alcohol and/or substance abuse structured screening and brief intervention services; 15 to 30 minutes	\$29.42
	G0397	Alcohol and/or substance abuse structured screening and brief intervention services; greater than 30 minutes	\$57.69
<b>Medicaid</b>	H0049	Alcohol and/or drug screening	\$24.00
	H0050	Alcohol and/or drug screening, brief intervention, per 15 minutes	\$48.00

Substance Abuse and Mental Health Services Administration. (2015a). *Coding for screening and brief intervention reimbursement*. Retrieved from <http://www.samhsa.gov/sbirt/coding-reimbursement>

***Screening for depression.*** Given the listed side effect of depression (5%) and suicidal behavior (5%) associated with XR-NTX use (Alkermes, 2013b; American Association for the Treatment of Opioid Dependence [AATOD], 2016), it is recommended to have the patient complete a depression screening tool such as the Patient Health Questionnaire-9 (PHQ-9) (Appendix H) (Kroenke & Spitzer, 2002). If there are any concerns regarding the presence of depression or other mental health disorders, a mental health evaluation should be conducted, and underlying depression or mental health disorders should be treated concurrently with substance abuse treatment.

***Screening for the appropriate XR-NTX candidate.*** SAMHSA has developed a pocket guide for MAT of opioid use disorder that has a checklist to aid in the selection of the appropriate patient (Appendix I) (2016a). They recommend assessing the need for MAT by determining the risk level of the patient's substance use disorder, which can be quantified by the NIDA-Modified ASSIST. Also, the healthcare provider should complete a patient history and exam and identify co-morbid health conditions. Providers also need to review their state's Prescription Drug Monitoring Program website to gain more clinical insight on the patient regarding prior prescription medication use. Recommended laboratory testing includes urine drug screen for current opioid and other drug use, urine test for alcohol, liver enzymes, serum bilirubin, serum creatinine, hepatitis screening, and HIV testing. Providers should also assess for each patient's need for medically managed withdrawal from opioids or alcohol (SAMHSA, 2016a). The Alkermes website for XR-NTX has a patient counseling checklist (Appendix F), which can be used to educate the patient about the use of XR-NTX and also helps the healthcare provider screen for the patient for appropriate treatment with XR-NTX (Alkermes, 2016). Patients who are candidates for MAT with XR-NTX must be free from opioid use for at least

seven to 10 days and possibly up to 21 days for longer acting prescription opioids such as buprenorphine and methadone, to prevent precipitation of opioid withdrawal. Patients should not be actively drinking alcohol when they receive their XR-NTX injection (Alkermes, 2016).

***Administration of XR-NTX.*** If the patient reports recent opioid use or there is a concern of precipitating withdrawal, you can consider offering a test dose of oral naltrexone using 12.5mg-25mg (AATOD, 2016). The Clinical Opiate Withdrawal Scale (COWS) (Appendix J) can be used to clinically assess for symptoms of opioid withdrawal before administration of XR-NTX and can be used to monitor for potential progression of withdrawal symptoms when utilizing a trial dose of oral naltrexone (Wesson & Ling, 2003). The Clinical Institute Withdrawal Assessment of Alcohol Scale-Revised (CIWA-ar) (Appendix K) can be used to assess the severity of alcohol withdrawal and the need for MAT.

After the screening, if the patient is found to be a candidate for XR-NTX, 380 mg of XR-NTX is given every 28 days via a deep intramuscular injection. It is mixed using the package contents which include the medication and diluent and is administered using the enclosed 1½-inch or 2-inch needle, depending on the amount of subcutaneous fat that is present. It is important to inject the medication into the muscle tissue to prevent an injection site reaction, which could be severe (Alkermes, 2015).

Through the duration and efforts of this project, XR-NTX is now predictably stocked in most Anchorage pharmacies. The billing for screening and administration of XR-NTX includes an evaluation and management office visit code and the XR-NTX administration fee in addition to a fee for SBIRT screening if appropriate. At one clinical setting, the healthcare providers found it beneficial to have a face-to-face visit with the client at their follow-up dosing to ensure accountability, support, and to assess client participation in a substance abuse treatment program.

**Community outreach.** Community outreach was the second activity listed within the logic model. Education, persuasion, and training were three of the nine recommended interventions utilized during this activity from the Behaviour Change Wheel (Appendix C) (Michie, van Stralen, & West, 2011). Outreach to community stakeholders needed all three of these interventions simultaneously to promote the use of XR-NTX. Outreach on the potential use of XR-NTX as a tool for substance abuse treatment occurred at Anchorage Therapeutic Courts, Partners Reentry Center, and local inpatient rehabilitation centers. Briefings and education on the XR-NTX access project occurred bi-monthly during Partners for Progress board meetings in Anchorage. A discussion included the referral process for immediate screening and administration of XR-NTX for appropriate candidates. Participation in panel discussions on prisoner reentry, including the use of XR-NTX by the project leader occurred at the March 2016 “Reducing Recidivism through Successful Reentry” conference and the May 2016 “Annual School on Addictions” conference in Anchorage, Alaska.

**Incentivisation and environmental restructuring.** The Behaviour Change Wheel interventions of both incentivisation and environmental restructuring were used to promote utilization of XR-NTX as a potential means to reduce recidivism along with structured support services and comprehensive substance abuse treatment programs. A total of 98 individuals were offered XR-NTX through the Partners Reentry Center during the implementation phase from September 15, 2015, through March 15, 2016. Of these, 60 accepted treatment with XR-NTX and 38 declined. Housing was provided for 82 of the total project population. Those accepting XR-NTX were often housed at the same facility.

**Funding.** The third activity in the logic model was to secure Medicaid status or ascertain funding for XR-NTX. The Patient Centered Affordable Care Act of 2010 made a legal

requirement that substance abuse treatment is covered by state Medicaid and other insurance plans available through the Health Insurance Exchange by 2014 (Office of National Drug Control Policy, n.d.). The 2015 Medicaid expansion in Alaska has increased access to substance abuse treatment including MAT for opioid or alcohol addiction. Those released from incarceration often return to their community without employment or medical insurance coverage. Thus, immediately upon release, most released prisoners are Medicaid eligible. Through education focusing on creating a fiscally sustainable project, applying for Medicaid is now a day of release priority for Partners Reentry Center. Partners Reentry Center has limited funds available to cover costs related to the initial screening and administration of XR-NTX until Medicaid coverage is received.

***Securing samples.*** The fourth activity in project's logic model was securing samples of XR-NTX to keep project costs low. Alkermes generously offered to provide samples of XR-NTX to support its use within the Alaska Department of Corrections (ADOC). These samples were distributed by Alkermes to willing providers.

***Modeling and enablement.*** Modeling and enablement are additional interventions from the Behaviour Change Wheel that aided the progression of this project. Information from Department of Correction programs from other states utilizing XR-NTX was presented to the ADOC for their review to generate interest regarding early access to XR-NTX. Other programs found that implementing XR-NTX before release from incarceration showed a reduction in the risk of recidivism (Florida Alcohol & Drug Abuse Association, 2015; Miller, 2013). ADOC expressed interest in exploring a pilot program for education, screening, and administration of XR-NTX in the halfway houses in Anchorage. The proposed onset for this program is

November 2016. ADOC also agreed to continue to explore the possibility of administering XR-NTX before releasing from incarceration.

### **Barriers and Challenges to Implementation**

This project sought to increase access to MAT with XR-NTX for a vulnerable population of recently released prisoners who battle addiction and opioid or alcohol abuse. Only giving the medication XR-NTX is insufficient to treat addiction entirely, but it is a safety net. Various reasons for declining XR-NTX are the initial barrier to implementing XR-NTX upon release from incarceration. The invasive nature of an injection and the inconvenience of taking the time to seek medical care were significant barriers. Regardless of insurance coverage, the cost of XR-NTX will remain a barrier as sample medication will not necessarily be available long term. A cost-benefit analysis of XR-NTX may show a sustainable program despite its high cost.

Development of a streamlined referral process from PRC was another barrier to overcome. It was essential to create a referral process from Partners Reentry Center to community healthcare providers that met the guidelines of patient privacy according to the Health Insurance Portability and Accountability Act of 1996. Providers and support staff required education and needed to experience positive outcomes to realize the importance of this project and create “buy-in” to provide a high level of support and care at the clinical level. One of the major barriers was recalling participants for the next due injection of XR-NTX. The onus of tracking and follow-up injections seemed to primarily fall on the medical provider despite the involvement of probation officers. Maintaining an accurate log and having support staff actively recall and engage individuals to return for follow-up injections proved worrisome and time-consuming.

While on probation, urine drug screens are often required for those with a history of substance abuse. Through board meetings held by Partners for Progress in Anchorage, probation officers were educated regarding the full opioid antagonist property of XR-NTX. For those who received XR-NTX and failed a urine drug screen for opioids, it was recommended by Partners Reentry Center that increased support rather than a return to incarceration was the best approach. This approach has become increasingly accepted.

### **Conclusion**

Implementation of this project began September 15, 2015. Although data collection ended September 15, 2016, those released from incarceration continue to be offered XR-NTX if they receive services and referral for XR-NTX from Partners Reentry Center. Most individuals who accepted XR-NTX during this project were able to receive Alaska Medicaid eligibility by the second or third XR-NTX injection, thus reducing the strain on valuable funding resources and medication samples. Clinical staff members involved were educated on screening and implementation of XR-NTX in the clinic setting and quickly became comfortable with the screening, injection, and patient tracking process. All involved in the implementation of this project became experts on the use of XR-NTX and the importance of a strong support system to ensure community success of the released prisoner.



## **Chapter VI: Evaluation of Project Outcomes**

This overall aim of this project was to implement existing evidence-based medicine and improve health outcomes. Access to extended-release injectable naltrexone (XR-NTX) was offered to recently released prisoners who received services to facilitate their community reentry at Partners Reentry Center (PRC) in Anchorage, Alaska. Retrospective data provided by PRC from September 15, 2015, to September 15, 2016 was evaluated. The outcomes of this project were very promising.

### **Outcome Measures**

Outcome measures listed on this project's Logic Model (Appendix B) were utilized to determine the success of implementing this evidence-based practice initiative. Recently released prisoners presenting to PRC were offered XR-NTX throughout the full year of this collaboration. Retrospective anonymous data was used to determine how many individuals accepted or declined XR-NTX. Rates of recidivism were also determined for the entire group population during the one-year time frame of this project. Recidivism rates were evaluated at the end of the one-year project for those who accepted XR-NTX in the first six months of the project. Demographic data was assessed. The data provided by PRC included information for most individuals regarding support measures to assist with housing, employment, and behavioral counseling. The effects of this additional support were evaluated.

### **Data Analysis and Results**

PRC offered XR-NTX to 98 recently released prisoners who self-identified as having a history of alcohol or opioid misuse during the time frame of this project. Of these, 62% ( $n = 61$ ) were male, 35% ( $n = 34$ ) were female, and gender was unknown for 3% ( $n = 3$ ). Figure 6.1 illustrates the distribution of the population by ethnicity, with 53% Caucasian, 31% Alaska

Native, and 16% other. Figure 6.2 illustrates the distribution by age, with 49% ( $n = 48$ ) of participants age 30 to 39.

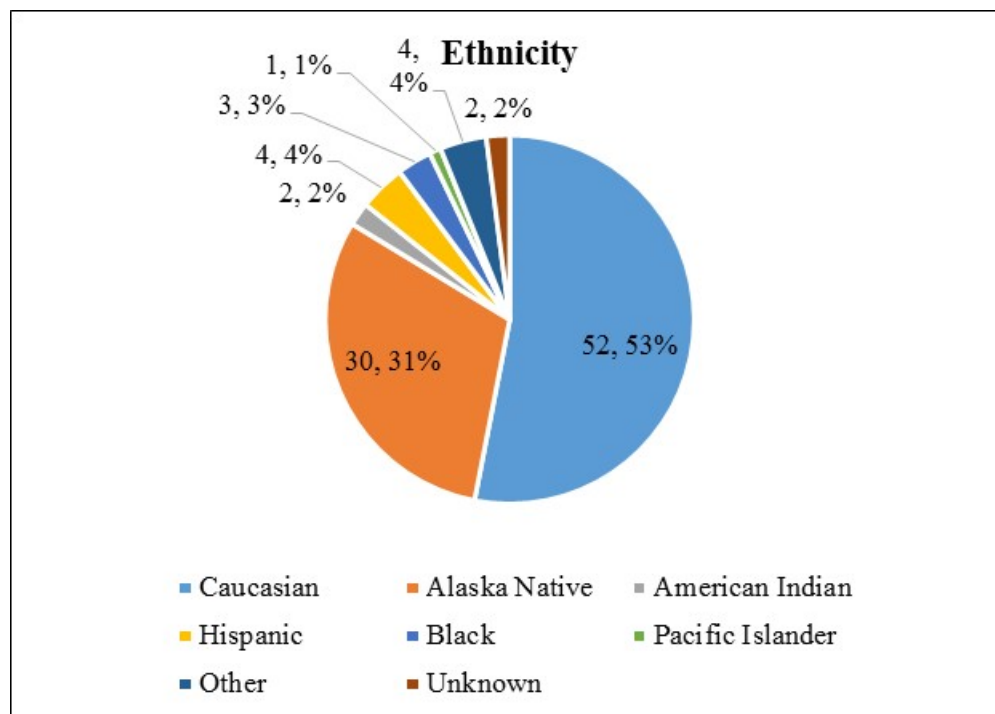


Figure 6.1. Distribution of project participants by ethnicity.

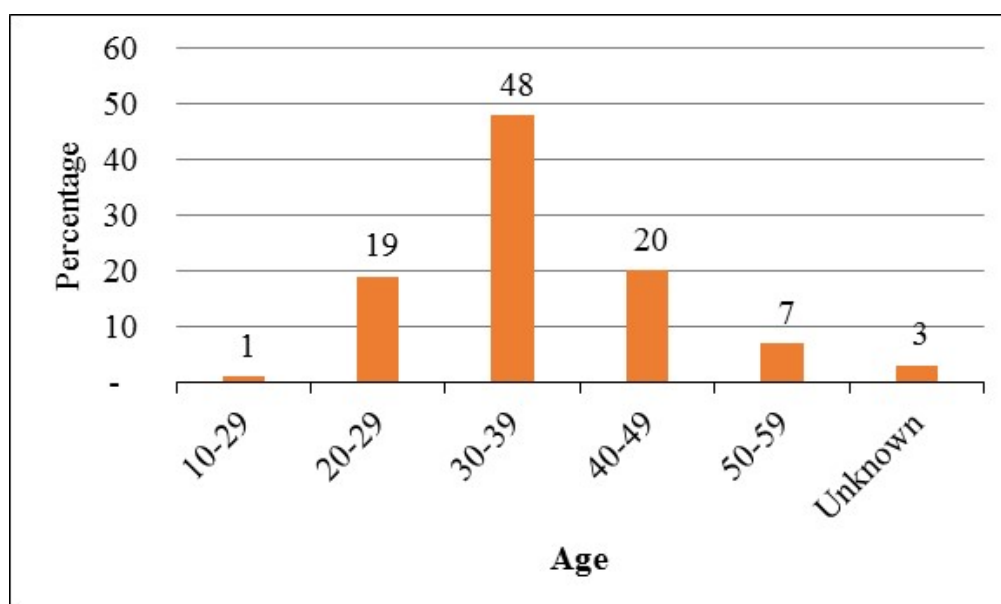


Figure 6.2. Distribution of project participants by age.

Data was collected for 12 months on PRC participants. It is not reliable to report recidivism rates on individuals who accepted XR-NTX in the final months. Those who accepted on the final day of data collection would not have had adequate time to show effectiveness of receiving XR-NTX. Ideally, this data will be followed longitudinally for comparison with known three-year recidivism rates. During the first six months, 53% of the total participants had been offered XR-NTX as part of their post-incarceration release plan. Figure 6.3 and Table 6.1 show the comparison of recidivism rates between those who accepted and those who refused XR-NTX, with 38% versus 95% recidivating six or more months after receiving one or more injections of XR-NTX. Results of the Chi-Square Test for Goodness and Fit of Association in showed a significant reduction in recidivism at 12 months for those who accepted XR-NTX during the first six months of data collection,  $\chi^2(1, N = 52) = 16.9, p = < .001$ .

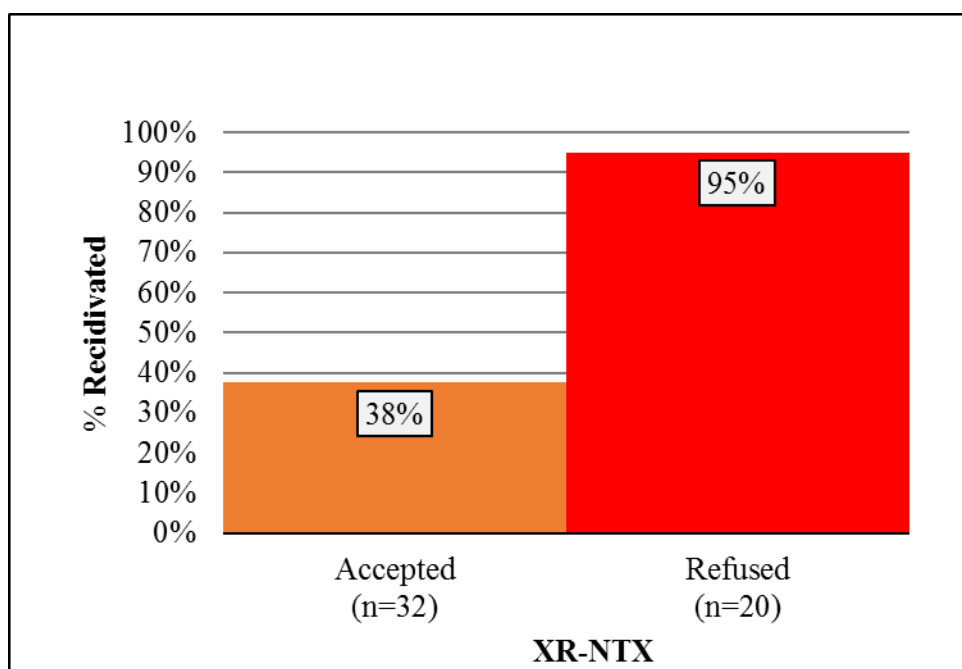


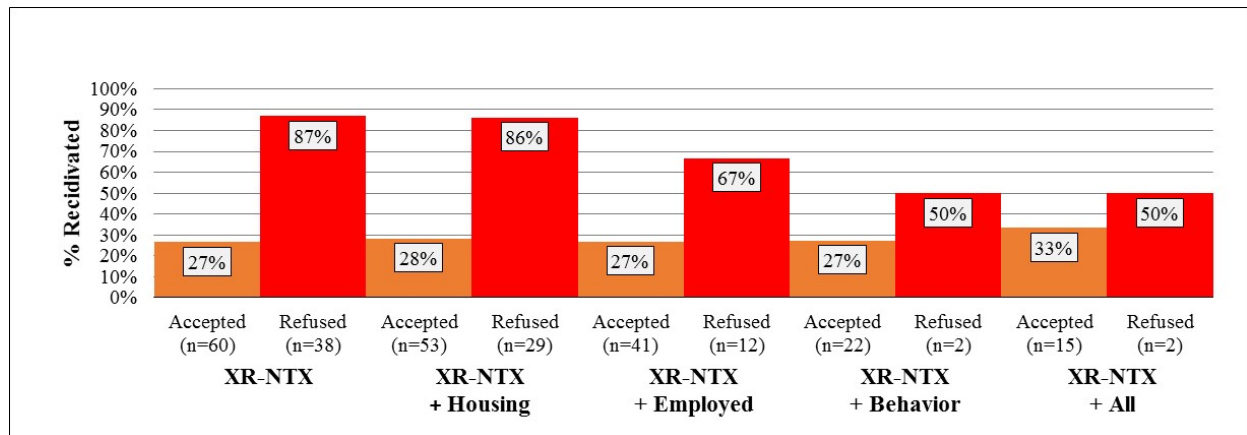
Figure 6.3. Recidivism rates at 12-months for participants enrolled during first six months.

Table 6.1

*A Comparison of Recidivism Rates at 12 Months Between Those Accepting and Refusing XR-NTX in First Six Months of Project Implementation*

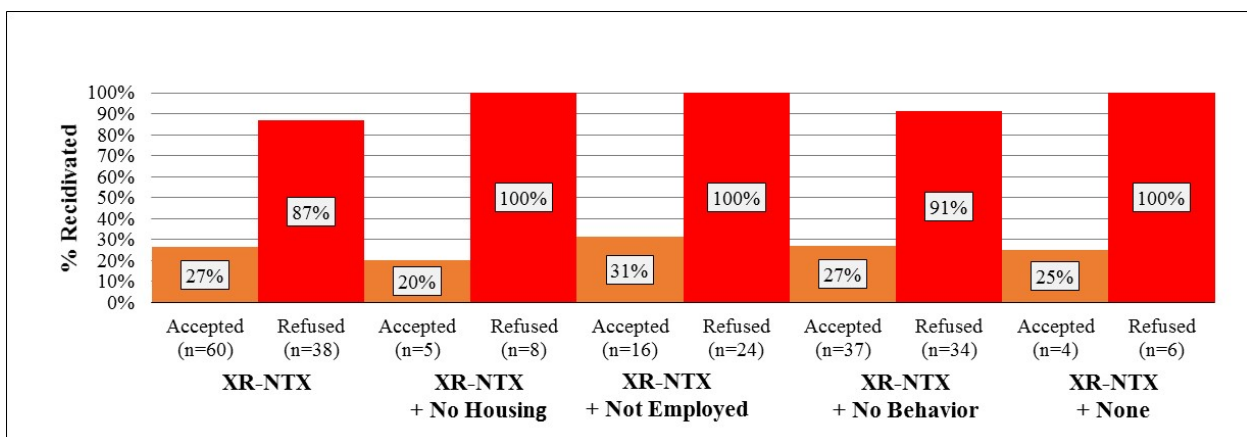
		XR-NTX $\geq$ 6 month		Total
		Accepted	Refused	
Recidivated	No	20	1	21
	Yes	12	19	31
Total		32	20	52

**Additional measures to reduce recidivism.** Although not identified as outcomes in the development of this project work, PRC offered important data regarding the prevalence of housing, employment, and participation in behavioral health counseling for their participants. It was explored whether these variables had an additional or independent impact on recidivism rates in comparison to the overall rates of recidivism for those who accepted or refused XR-NTX. Figure 6.4 depicts those who accepted XR-NTX ( $n = 60$ ) along with housing, employment, behavioral counseling, or all three. The results showed negligible change in recidivism. This lack of change in recidivism may be related to the short-term follow-up of participants. Also of interest, of those who refused XR-NTX yet had employment ( $n = 12$ ), 67% recidivated versus 87% for the entire population that refused XR-NTX ( $n = 38$ ). Additional participants will be needed to create a large enough population to evaluate statistical significance with regard to these outcomes.



*Figure 6.4.* Comparison of Recidivism Rates Among Project Participants Who Accepted or Refused XR-NTX and Had Additional Support Measures.

Another comparison was made between those who accepted XR-NTX and had no additional support measures. It was interesting to see that recidivism rates did not vary much between the groups who had support as shown in Figure 6.4 and those who did not have additional support services as illustrated in Figure 6.5. Again, the number of individuals in each category was not large enough to show a statistically meaningful correlation. Although it may seem obvious, Figure 6.5 also shows that doing nothing leads to nearly 100% recidivism.



*Figure 6.5.* Comparison of Recidivism Rates Among Project Participants Who Accepted or Refused XR-NTX and Had No Additional Support Measures.

## Discussion of Results

Using XR-NTX in the released prisoner population through collaboration between PRC and community-based primary care providers in Anchorage, Alaska showed a statistically significant reduction in recidivism in those who accepted XR-NTX in their post-release plan. Only one person who refused XR-NTX remained in their community at greater than six months compared to 20 individuals who received XR-NTX and did not recidivate. The daily rate of a hard bed in the Alaska prison system costs \$158 a day (Gutierrez, 2015). The reduction in recidivism due to XR-NTX if these 20 individuals stay in their community for a full year will save the State of Alaska over \$1 million. The implementation of early access to XR-NTX upon release from incarceration proved an important application of evidence-based practice.

**Limitations.** There were limitations to this retrospective evidence-based practice implementation project. In general, evidence-based practice outcomes in a community are not generalizable to other populations (Melnik & Fineout-Overholt, 2015). The number of people in this project was too small to evaluate the independent effects of other variables that affect recidivism, although emerging trends were seen providing a recommendation for future research. PRC stated it was difficult to obtain and track data on this population. Specifically, to document how many injections of XR-NTX each participant received. Self-selection bias is also a limitation to the generalizability of this data as those who opted to utilize XR-NTX may have been highly motivated and less likely to recidivate overall in comparison to those who did not accept XR-NTX. Following this data over three years will allow for comparison to the ADOC 2011 three-year recidivism rate of 63% (Gutierrez, 2015).

**Conclusion**

The use of XR-NTX is a substance abuse treatment that follows evidenced-based medicine. The American Society of Addiction Medicine national practice guideline recommends using Medication-Assisted Treatment, such as XR-NTX, in alcohol and opioid abuse treatment (2015). The data in this project should be followed longitudinally to meet the other project outcome of comparing present and long-term criminal recidivism rates with acceptance or refusal of XR-NTX. Other data provided to this project leader regarding employment, housing, and behavioral counseling could be useful in planning future programs that would ensure the best community success for the released prisoner if followed over time.

## **Chapter VII: Implications for Nursing Practice**

Advanced nursing degrees will be at the forefront of changes in healthcare in the United States. In 2008 the Institute of Medicine (IOM) and the Robert Wood Johnson Foundation collaborated to examine nursing and its potential contribution to meet the challenges brought forth by a call for health care reform that would improve healthcare outcomes and reduce healthcare expenditure (Institute of Medicine [IOM], 2011). The document “The Future of Nursing: Leading Change, Advancing Health” (IOM, 2011) calls upon nurses to move into leadership roles to influence healthcare outcomes and policy change. The IOM cites a Gallup Poll from 2010 “Nursing Leadership from Bedside to Boardroom: Opinion Leaders’ Perceptions” which suggests that while nurses are trusted health professionals, they are not yet viewed as capable of improving access to healthcare, influencing reform, or having a strong voice in the realm of health policy. The IOM calls upon nursing to make changes to this perception and reality. The evolution of the Doctorate of Nursing Practice (DNP) degree will help this transformation to nurses as leaders in the health care community.

### **Essentials of Doctoral Education for Advanced Nursing Practice**

In October 2006, the American Association of Colleges of Nursing (AACN) published the eight essentials for nursing practice to attain in the DNP degree program.

**Essential I: Scientific underpinnings for practice.** The first essential of the DNP degree strives to “Integrate nursing science with knowledge from ethics, the biophysical, psychosocial, analytical, and organizational sciences as the basis for the highest level of nursing practice” (AACN, 2006, p. 10). This project utilized scientific evidence-based medicine to improve healthcare by providing access to extended-release injectable naltrexone (XR-NTX) to



an underserved population by collaborating with other community stakeholders working with released prisoners.

**Essential II: Organizational and systems leadership for quality improvement and systems thinking.** This area of competency is meant to improve patient outcomes beyond the DNP student's current practice setting with a goal to improve health for a larger population within the community by creating a plan to implement a healthcare initiative, and working with other organizations to facilitate this improvement (AACN, 2006). A primary care family nurse practitioner would not typically work directly with individuals immediately released from incarceration. However, there was an opportunity to provide these people with access to XR-NTX upon release, which was a medical treatment not readily accessible. Meeting with the non-profit group, Partners Reentry Center (PRC), in September 2015 helped identify issues leading to recidivism. Brainstorming was conducted to find ways to overcome this barrier and ease access to XR-NTX to aid the success of the released prisoner in their community. Attending bi-monthly board meetings at PRC helped provide the overall picture of reducing recidivism while ensuring the project was financially sustainable.

**Essential III: Clinical scholarship and analytical methods for evidence-based practice.** This essential embodies the process of nursing research (AACN, 2006). This project started due to a perceived need to reduce substance-related crime and recidivism. A literature review was conducted to evaluate existing research surrounding the use of XR-NTX to prevent recidivism. The body of evidence is still emerging in regards to this topic. The data from this project show that XR-NTX is a promising tool to help prevent recidivism for those who are highly motivated to receive the monthly injection. The data from this ongoing project have been disseminated to various healthcare care clinicians in the Anchorage community, substance abuse

treatment programs, and to the Alaska Nurse Practitioner's Association annual conference. It is important to have widespread dissemination of this important nursing evidence-based project work, especially given the limited body of published research in regards to the use of XR-NTX and its potential for recidivism reduction.

**Essential IV: Information systems/technology and patient care technology for the improvement and transformation of healthcare.** The use of technology for this project was limited to the data collection process that was conducted by PRC. The prisoner population is a considered a vulnerable population according to the Institutional Review Board. Thus data provided for the purpose of this project had to be de-identified to ensure confidentiality (U.S. Department of Health and Human Services Office for Human Research Protections, 2003). Mentoring from the project leader was required to guide what data was needed to provide meaningful project outcomes. At the end of this project, suggestions were made for future data collection and ongoing research possibilities. A referral process was created from PRC to community healthcare providers that met the guidelines of patient privacy according to the Health Insurance Portability and Accountability Act of 1996. Also, providers administering XR-NTX should utilize the electronic health record system to schedule patients for four-week follow-up appointments for future XR-NTX injections or use the electronic health record to set reminders to contact patients receiving XR-NTX before the due date of their next dose.

**Essential V: Health care policy and advocacy in healthcare.** According to the AACN “the DNP graduate is able to design, implement and advocate for health care policy that addresses issues of social justice and equity in health care” (2006, p. 14). Using a theoretical model of care, the Behavioural Change Wheel (Appendix C), allowed for a systematic approach to implementing a healthcare initiative to advocate for a change in health policy (Michie, van

Stralen, & West, 2011). The Alaska Department of Corrections (ADOC) is now considering the use of XR-NTX in halfway housing with implementation set to occur in November, 2016.

Several meetings with the medical director from the ADOC facilitated the development of a draft policy for future screening and administration of XR-NTX.

**Essential VI: Interprofessional collaboration for improving patient and population health outcomes.** This essential highlights the importance of collaboration between professional entities to truly improve population health (AACN, 2006). The Interprofessional Education Collaborative Expert Panel states “The goal of this interprofessional learning is to prepare all health professions students for *deliberatively working together* with the common goal of building a safer and better patient-centered and community/population-oriented U.S. health care system” (2011, p. 3). It was a meaningful experience to draw on the expertise of numerous professionals to solve a public health problem and reduce recidivism.

**Essential VII: Clinical prevention and population health for improving the nation’s health.** This project clearly meets this DNP essential that brings focus to the importance of preventing adverse health outcomes and improving population health regardless of culture or socioeconomic variables (AACN, 2006). XR-NTX provides a safety net to prevent relapse of opioid or alcohol use, which in turn prevented recidivism. Although treatment with XR-NTX is costly, all participants in this project were eligible regardless of insurance or ability to pay and thus eliminated gaps in their capacity to receive care. Perhaps most important of all, those involved in this project were able to view addiction as a disease state that was not a reflection of personal choice.

**Essential VIII: Advanced nursing practice.** The DNP degree promotes specialization within the advanced nursing practice. Throughout the DNP project, there is an opportunity to

become a nurse leader and expert on a particular topic, thus becoming a community expert and resource (AACN, 2006). This level of leadership has the power to change health care for the patient up to the systems level of healthcare delivery while utilizing a strong nursing background. Implementing this project offering early access to XR-NTX upon release from incarceration required a high degree of healthcare ethics and cultural awareness to work with a vulnerable population. Existing literature was reviewed and utilized as a basis for implementing a comprehensive program that would improve health outcomes through an interprofessional approach. This project fully realized the importance of building professional relationships and using the strengths of others. This project will serve as a basis for additional nursing projects on alcohol and opioid misuse. Seeing policy changes emerge within the ADOC based on the data from this project is the culmination of the efforts in this project.

### **Implications**

The 2015 National Drug Control Strategy (Office of National Drug Control Policy, 2015) states substance misuse is a medical disorder that is preventable and treatable, much like any other illness. MAT is underutilized, mainly due to lack of knowledge regarding medication options and their benefit in the treatment of addicts (National Association of Drug Court Professionals, 2013). Nursing leadership is well suited to implement an evidence-based project to improve population health in their community. The data from this project providing early access to XR-NTX upon release from incarceration shows the immense power of implementing evidence-based practice through community collaboration to improve population health.

Positive health outcomes are also more cost effective. The Institute for Healthcare Improvement (IHI) (2016) discusses a triple aim approach at improving healthcare: Improve population health, improve the patient experience in healthcare, and reduce per capita

expenditure on healthcare. The IHI states that all three dimensions need to be simultaneously considered to achieve notable improvement in healthcare in the United States. When considering the implementation of an evidence-based guideline into the practice setting, it is critical to recognize the value of the guideline in regards to safety, improved patient outcomes, and patient satisfaction, all while maintaining a cost that is reasonable (Anderson et al., 2014). The use of XR-NTX in the released prisoner population has potential cost-saving benefit to the State of Alaska.

### **Barriers to Implementation**

Implementing early access to XR-NTX upon release from incarceration required extensive collaboration between PRC and various community healthcare providers. This collaborative process was not without challenges. One primary care facility that patients are referred to has a policy that requires a one-month trial and failure of oral naltrexone before administration of XR-NTX. This system is, of course, counterintuitive to the goals of this project. Patients who typically received care at this facility received a referral to another primary care facility in town that did not have this stipulation for use. Another challenge encountered was transportation to the primary care provider offices. While many facilities are on the bus routes, the connections were not convenient and thus created a barrier to receiving the first injection of XR-NTX. When necessary, PRC opted to send individuals in a paid taxi using their grant funds. A future solution will be the upcoming opening of a primary care facility nearer to downtown Anchorage, which will improve access to care.

As more individuals seek XR-NTX in their treatment and release plan, another barrier is the general lack of primary care providers who have received education on substance abuse and the use of XR-NTX. Hopefully, more primary care providers become interested in screening and

treatment for substance abuse, and outreach is ongoing to community providers interested in or involved in drug or alcohol misuse.

Procuring samples and ensuring their availability was intermittently a challenge to providing care and optimizing this project. Those working with released prisoners now place greater emphasis on applying early for Alaska State Medicaid eligibility. Without insurance coverage, the cost of XR-NTX is certainly a barrier. However, expansion of Alaska Medicaid eligibility significantly increased access to substance abuse treatment, and many of those previously incarcerated qualify for Medicaid benefits upon release. The costs associated with implementing this pilot program would be far less than daily cost of incarceration, which was \$158.67 in 2014 (Gutierrez, 2015).

Historically, XR-NTX is not recommended as a stand-alone treatment for opioid or alcohol abuse. It works in conjunction with a comprehensive substance abuse program. Gaining access to evidence-based substance abuse treatment programs remains an ongoing barrier in the State of Alaska because there are not enough behavioral health resources to meet the demands. The Affordable Care Act requires the coverage of substance abuse treatment as a benefit provided by insurance policies ascertained through the Health Insurance Exchange or State Medicaid (Office of National Drug Control Policy, n.d.). However, providers often limit access to care for those underinsured with Alaska State Medicaid or Medicare insurance policies. PRC has increased their efforts in providing Moral Reconciliation Therapy and Peer-To-Peer groups as a means to provide a substance abuse program for recently released prisoners. Local 12-step programs through Narcotics Anonymous and Alcoholics Anonymous are another free option. There may be future grant funding available to facilitate behavioral health services in collaboration with other community partners.

**Conclusion**

Nurses and nurse practitioners are often on the frontline of patient care. A quality improvement initiative will be successful with strong leadership to influence change. Initiating early access to XR-NTX requires more healthcare providers who are willing to screen and utilize medically assisted treatment to aid in the treatment of alcohol or opioid abuse. With the assistance of PRC and other existing and new community partners, this project will drive change to reduce barriers and create solutions to implementing early access to XR-NTX with a long-term goal to reduce recidivism. This initiative will drive funding and policy change to further efforts towards access to XR-NTX. This project clearly addresses all of the Essentials for the Doctor of Nursing Practice degree.

### **Chapter VIII: Summary and Conclusion**

Alaska's Department of Corrections (ADOC) facilities are at capacity, with an 11% growth expected by 2018 (Gutierrez, 2015). Published after the onset of this project, the Alaska Criminal Justice Commission's 2015 Justice Reinvestment Report includes 21 recommendations for reducing the ADOC's prisoner population by 2024 (Coghill, 2016). The 21 recommendations will: "implement evidence-based pretrial practices; focus prison beds on serious and violent offenders; strengthen supervision and interventions to reduce recidivism; ensure oversight and accountability; and advance crime victim priorities" (Alaska Criminal Justice Commission, 2015). The Justice Reinvestment Report became the basis for Alaska Senate Bill (SB) 91 (2015-2016), which aims to reform criminal justice, improve public safety, and save an estimated \$380 million dollars over the next decade (Coghill, 2016). During the course of this project implementation, SB 91 passed on April 9, 2016, with a 16-2 vote. This important legislation will lead the way for sentencing and parole reform and improving services upon release from prison to prevent recidivism.

Public health policy can change population health. The adoption of health policies shapes the allocation of funding which allows for successful implementation of a proposed program (Centers for Disease Control and Prevention [CDC], 2015b). On February 2, 2016, President Obama proposed \$1.1 billion in spending beginning in the FY2017 budget to address our nation's drug epidemic. The goal of the funding is to improve access to treatment for substance abuse across the nation through the use of medication-assisted treatment (MAT) to combat a growing epidemic of opioid and heroin abuse (The White House, 2016b). This funding will hopefully heighten the awareness and utilization of MAT throughout the nation.



A high percentage of those incarcerated in the ADOC are directly due to alcohol (12.32%) and drugs (12.16%) (Alaska Department of Corrections, 2015). Providing access to extended-release injectable naltrexone (XR-NTX) upon release from incarceration has proved an important measure in reducing recidivism in the State of Alaska.

### **Key Points**

This project has proved a very timely topic as rates of opioid use are soaring, and rates of alcohol misuse in the State of Alaska remains high. Heroin addiction has doubled in the past decade and is an epidemic (CDC, 2015a), yet alcohol remains the most widely used and abused drug in the United States and is the third leading lifestyle-related cause of death in the U.S. (State of Alaska, 2015a). The U.S. Surgeon General, Vivek Murthy, has created the “Turn the Tide Rx” movement to reduce the opioid crisis in the U.S. All healthcare providers are asked to sign a pledge to help combat this growing epidemic through safe opioid prescribing (Surgeon General of the United States, n.d.).

MAT remains vastly underutilized as an adjunct in substance abuse treatment. Only one out of 10 substance-addicted individuals (excluding nicotine) receives any treatment at all (CASA Columbia, 2010). Although there is not a “one size fits all” in healthcare, this project shows that using MAT, specifically XR-NTX, is a valuable support tool in the recovery from substance or alcohol addiction. The outcomes from this project have aided the task of educating community providers about the potential of using XR-NTX in recovery from substance and alcohol abuse as it promotes abstinence while working through a formal treatment program. Healthcare professionals at the front lines of treatment are in a prime position to screen for substance abuse history and begin the conversation about treatment options. Education of the patient diagnosed with substance abuse is also imperative as they may lack knowledge of the

available treatment options. Knowledge is the key to implementing changes in healthcare practice.

Providing access to XR-NTX upon release from incarceration with a goal to reduce recidivism seemed a simple task at the outset. However, building collaborative relationships with all involved in prisoner release was the hallmark of this project. The significant reduction in recidivism demonstrated in this project shows the strength of community collaboration.

### **Conclusion**

Along with comprehensive community resources to help the released prisoner successfully reenter their community, XR-NTX may be one tool to reduce recidivism and the burden on ADOC facilities. The ADOC, those previously incarcerated with substance abuse, and Alaska's communities would be well-served to continue this collaborative project. Another goal would be to initiate a program that focuses on the use of XR-NTX before prisoners are released from incarceration to further reduce the risk of recidivism due to immediate alcohol or opioid misuse upon release. Beyond monetary savings, XR-NTX has the potential to contribute to reducing deaths related to opioid overdose, reduce crime in the community, and improve the lives of those with a history of substance or alcohol misuse. President Obama aptly proclaimed "during Prescription Opioid and Heroin Epidemic Awareness Week, we pause to remember all those we have lost to opioid use disorder, we stand with the courageous individuals in recovery, and we recognize the importance of raising awareness of this epidemic" (The White House, 2016a).

### References

- American Society of Addiction Medicine. (2015). *The ASAM national practice guideline for the use of medications in the treatment of addiction involving opioid use*. Retrieved from <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/national-practice-guideline.pdf?sfvrsn=18>
- Alanis-Hirsch, K., Croff, R., Ford, J. H., Johnson, K., Chalk, M., Schmidt, L., & McCarty, D. (2015). Extended-release naltrexone: A qualitative analysis of barriers to routine use. *Journal of Substance Abuse Treatment*, doi:10.1016/j.jsat.2015.10.003
- Alaska Court System. (n.d.). *Therapeutic courts information*. Retrieved from <http://www.courts.alaska.gov/therapeutic/index.htm#general>
- Alaska Criminal Justice Commission. (2015). *Justice reinvestment report*. Retrieved from [http://www.ajc.state.ak.us/sites/default/files/imported/acjc/recommendations/ak\\_justice\\_reinvestment\\_initiative\\_report\\_to\\_acjc\\_12-9.pdf](http://www.ajc.state.ak.us/sites/default/files/imported/acjc/recommendations/ak_justice_reinvestment_initiative_report_to_acjc_12-9.pdf)
- Alaska Department of Corrections. (2014). *Trust beneficiaries in Alaska's department of corrections*. South Portland, Maine: Hornby Zeller Associates, Inc.
- Alaska Department of Corrections. (2015). *2015 offender profile*. Retrieved from <http://www.correct.state.ak.us/admin/docs/2015profile.pdf>
- Alaska Judicial Council. (2012). *Recidivism in Alaska's therapeutic courts for addictions and department of corrections institutional substance abuse programs*. Retrieved from [http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&cad=rja&uact=8&ved=0ahUKEwjMrbtb\\_rtzJAhVR92MKHXspCloQFggvMAM&url=http%3A%2F%2Fwww.ajc.state.ak.us%2Freports%2F2012programrecid.pdf&usg=AFQjCNG1Aseqmu7kh9R6pPF5nENJOsTNkw](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&cad=rja&uact=8&ved=0ahUKEwjMrbtb_rtzJAhVR92MKHXspCloQFggvMAM&url=http%3A%2F%2Fwww.ajc.state.ak.us%2Freports%2F2012programrecid.pdf&usg=AFQjCNG1Aseqmu7kh9R6pPF5nENJOsTNkw)

Alaska Judicial Council. (2007). *Criminal recidivism in Alaska*. Retrieved from

[www.ajc.state.ak.us/reports/1-07CriminalRecidivism.pdf](http://www.ajc.state.ak.us/reports/1-07CriminalRecidivism.pdf)

Alaska State Troopers' Alaska Bureau of Investigation Statewide Drug Enforcement Unit.

(2014). *Annual drug report*. Received from

<http://dps.alaska.gov/AST/ABI/docs/SDEUreports/2014%20Annual%20Drug%20Report.pdf>

Aletraris, L., Bond Edmond, M., & Roman, P. M. (2015). Adoption of XR-NTX in U.S.

substance use disorder treatment programs. *Journal of Studies on Alcohol and Drugs*,

76(1), 143-151. doi:10.15288/jsad.2015.76.143

Alkermes. (2013a, Jan 08). *Fair Disclosure Wire*. JPMorgan global healthcare conference -

final. Retrieved from

<http://search.proquest.com.proxy.consortiumlibrary.org/docview/1271959560?accountid=14473>

Alkermes. (2013b). *Safety and side effects of Vivitrol*. Retrieved from

<http://www.vivitrol.com/About/SafetyAndSideEffects>

Alkermes. (2013c). *Vivitrol: Evaluation of efficacy and safety in opioid dependence*. Retrieved

from <http://www.vivitrol.com/HCP/Efficacy/OpioidDependence>

Alkermes. (2015). *Vivitrol: Highlights of prescribing information*. Retrieved from

[https://www.vivitrol.com/Content/pdf/prescribing\\_info.pdf](https://www.vivitrol.com/Content/pdf/prescribing_info.pdf) Alkermes. (2016). *Patient counseling information*. Retrieved from

<https://www.vivitrol.com/HCP/VivitrolResources/PatientCounselingChecklist>

American Association for the Treatment of Opioid Dependence. (2016). *AATOD guidelines for*

*using naltrexone (Vivitrol) in OTPs*. Retrieved from

<http://www.aatod.org/policies/policy-statements/aatod-guidelines-for-using-naltrexone-vivitrol-in-otps/>

American Association of Colleges of Nursing. (2006). *The essentials of doctoral education for advanced nursing practice*. Retrieved from

<http://www.aacn.nche.edu/publications/position/DNPEssentials.pdf>

Anderson, J. L., Heidenreich, P. A., Barnett, P. G., Creager, M. A., Fonarow, G. C., Gibbons, R.

J.. . (2014). ACC/AHA statement on cost/value methodology in clinical practice guidelines and performance measures: A report of the American college of cardiology/American heart association task force on performance measures and task force on practice guidelines. *Circulation*, 129(22), 2329-2345.

doi:10.1161/CIR.0000000000000042

Andrews, D. A., & Bonta, J. (1995). *LSI-R the Level of Service Inventory–Revised user’s manual*. North Tonawanda, NY: Multi-Health Systems. Retrieved from

<http://www.mhs.com/product.aspx?gr=saf&id=overview&prod=lsi-r>

Aos, S., & Drake, E. (2013). *Prison, police, and programs: Evidence-based options that reduce crime and save money* (Doc. No. 13-11-1901). Olympia: Washington State Institute for Public Policy.

Beck, E. (2015, May 25). DHHR developing opiate addiction treatment program. *Charleston Gazette-Mail*. Retrieved from

<http://www.wvgazettemail.com/article/20150525/GZ01/150529605>

Boots, M. T. (2013, October 2). New prisoner re-entry center takes aim at criminal recidivism.

*Alaska Dispatch News*. Retrieved from <http://www.adn.com/article/20131002/new-prisoner-re-entry-center-takes-aim-criminal-recidivism>

CASAColumbia. (2012). *Addiction medicine: Closing the gap between science and practice*.

Retrieved from <http://www.casacolumbia.org/download/file/fid/1177>

Centers for Disease Control and Prevention. (2015a). Today's heroin epidemic. Retrieved from

<http://www.cdc.gov/vitalsigns/heroin/>

Centers for Disease Control and Prevention. (2015b). Public health policy. Retrieved from

<http://www.cdc.gov/stltpublichealth/policy/>

Centers for Medicare & Medicaid Services. (2014). *Coverage and delivery of adult substance abuse services in Medicaid managed care*. Retrieved from

[https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=0ahUKEwjX36mZ4o\\_KAhVW5mMKHW5tBBoQFgheMAQ&url=https%3A%2F%2Fwww.medicicaid.gov%2Fmedicaid-chip-program-information%2Fby-topics%2Fbenefits%2Fdownloads%2Fcms-adult-substance-abuse-services-coverage.pdf&usg=AFQjCNH6cpMsdPAOSCnqrQL0Q738RMAiEgff](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=0ahUKEwjX36mZ4o_KAhVW5mMKHW5tBBoQFgheMAQ&url=https%3A%2F%2Fwww.medicicaid.gov%2Fmedicaid-chip-program-information%2Fby-topics%2Fbenefits%2Fdownloads%2Fcms-adult-substance-abuse-services-coverage.pdf&usg=AFQjCNH6cpMsdPAOSCnqrQL0Q738RMAiEgff)

Coghill, J. (2016, April 9). *Criminal justice reform to maximize public safety return on corrections dollars*. Retrieved from

<https://www.alaskasenate.org/2016/press/news/coghill-safety-return-on-corrections-dollars>

Council of State Governments. (2015). *Housing*. Retrieved from

<https://csgjusticecenter.org/reentry/issue-areas/housing/>

Council of State Governments. (n.d.). *Report of the re-entry policy council: Charting the safe and successful return of prisoners to the community*. Retrieved from

<https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwiy5a2EmabKAhVU5WMKHc4yDcYQFggdMAA&url=https%3A%2F%2Fcsgjusticece>

- nter.org%2Fwp-content%2Fuploads%2F2013%2F03%2FReport-of-the-Reentry-Council.pdf&usg=AFQjCNHhbWJo2dV4F1xwxEJQu4ge5sI1jw
- Coviello, D. M., Cornish, J. W., Lynch, K. G., Boney, T. Y., Clark, C. A., Lee, J. D., & O'Brien, C. P. (2012). A multisite pilot study of extended-release injectable naltrexone treatment for previously opioid-dependent parolees and probationers. *Substance Abuse*, 33(1), 48-59. doi:10.1080/08897077.2011.609438
- Crits-Christoph, P., Lundy, C., Stringer, M., Gallop, R., & Gastfriend, D. R. (2015). Extended-release naltrexone for alcohol and opioid problems in Missouri parolees and probationers. *Journal of Substance Abuse Treatment*, 56, 54. doi:10.1016/j.jsat.2015.03.003
- Drugs.com. (2015). *Vivitrol approval history*. Retrieved from <http://www.drugs.com/history/vivitrol.html>
- Durose, M. R., Cooper, A. D., & Snyder, H. N. (2014). *Recidivism of prisoners released in 30 states in 2005: Patterns from 2005 to 2010* (Bureau of Justice Statistics Publication No. NCJ 244205). Retrieved from [http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwiR2afa0dDJAhUG32MKHSPfCKEQFgggMAA&url=http%3A%2F%2Fwww.bjs.gov%2Fcontent%2Fpub%2Fpdf%2Fprts05p0510.pdf&usg=AFQjCNFNkF1uK\\_1f0559N84Q705c6pJ73w](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwiR2afa0dDJAhUG32MKHSPfCKEQFgggMAA&url=http%3A%2F%2Fwww.bjs.gov%2Fcontent%2Fpub%2Fpdf%2Fprts05p0510.pdf&usg=AFQjCNFNkF1uK_1f0559N84Q705c6pJ73w)
- Finigan, M.W., Perkins, T., Zold-Kilbourn, P., Parks, J., & Stringer, M. (2011). Preliminary evaluation of extended-release naltrexone in Michigan and Missouri drug courts. *Journal of Substance Abuse Treatment*, 41(3), 288-93. doi: 10.1016/j.jsat.2011.04.003
- Finkler, S. A., Jones, C., & Kovner, C. T. (2013). *Financial management for nurse managers and executives - E-book* (4th ed.). US: Saunders.

Florida Alcohol & Drug Abuse Association. (2015). *Provider eligibility criteria*

*VIVITROL® for addicted offenders*. Retrieved from

<http://www.fadaa.org/vivitrol/documents/ProviderEligibilityCriteria.pdf>

The Foundation for Government Accountability. (2013). *Why Medicaid expansion is wrong for*

*Alaska*. Retrieved from <http://thefga.org/research/why-medicaid-expansion-is-wrong-for-alaska/>

Gordon, M. S., Kinlock, T. W., & Miller, P. M. (2011). Medication assisted treatment research

with criminal justice populations: Challenges of implementation. *Behavioral Sciences & the Law*, 29(6), 829–845. [doi.org/10.1002/bsl.1015](https://doi.org/10.1002/bsl.1015)

Gordon, M. S., Kinlock, T. W., Vocci, F. J., Fitzgerald, T. T., Memisoglu, A., & Silverman, B.

(2015). A phase 4, pilot, open-label study of VIVITROL® (extended-release naltrexone XR-NTX) for prisoners. *Journal of Substance Abuse Treatment*, 59, 52-58. doi: 10.1016/j.jsat.2015.07.005

Gutierrez, C. (2015). *2015 recidivism reduction plan: Cost-effective solutions to slow prison population growth and reduce recidivism*. Retrieved from

[http://www.correct.state.ak.us/commish/docs/HB266%20-%20Recidivism%20Reduction%20Plan%20Report%20\(2015\).pdf](http://www.correct.state.ak.us/commish/docs/HB266%20-%20Recidivism%20Reduction%20Plan%20Report%20(2015).pdf)

Hanlon, T. (2015, July 3). With patients turned away, Anchorage Neighborhood Health Center tackles staff shortage. *Alaska Dispatch News*. Retrieved from

<http://www.adn.com/article/20150703/patients-turned-away-anchorage-neighborhood-health-center-tackles-staff-shortage>

Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.



- Institute of Healthcare Improvement. (2016). *IHI triple aim initiative*. Retrieved from <http://www.ihl.org/engage/initiatives/TripleAim/Pages/default.aspx>
- Institute of Medicine. 2011. *The future of nursing: Leading change, advancing health*. Washington, DC: The National Academies Press. Retrieved from [http://www.nap.edu/catalog.php?record\\_id=12956](http://www.nap.edu/catalog.php?record_id=12956)
- Interprofessional Education Collaborative Expert Panel. (2011). *Core competencies for interprofessional collaborative practice: Report of an expert panel*. Washington, D.C.: Interprofessional Education Collaborative. Retrieved from <http://www.aacn.nche.edu/education-resources/IPECReport.pdf>
- Jackson, H., Mandell, K., Johnson, K., Chatterjee, D., & Vanness, D. J. (2015). Cost effectiveness of injectable extended release naltrexone compared to methadone maintenance and buprenorphine maintenance treatment for opioid dependence. *Substance Abuse*, 36(2), 226-231. doi:10.1080/08897077.2015.1010031
- James, N. (2015). *Offender reentry: Correctional statistics, reintegration into the community, and recidivism* (Congressional Research Service Publication No. RL34287). Retrieved from [http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&cad=rja&uact=8&ved=0ahUKEwiurNW6zdDJAhUI2WMKHcPSCtUQFggyMAM&url=http%3A%2F%2Fwww.justicepolicy.org%2Fimages%2Fupload%2F08\\_01\\_rep\\_drugtx\\_ac-ps.pdf&usg=AFQjCNELoKrtA7QE7dvo1rCzfBExa1YzMQ](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&cad=rja&uact=8&ved=0ahUKEwiurNW6zdDJAhUI2WMKHcPSCtUQFggyMAM&url=http%3A%2F%2Fwww.justicepolicy.org%2Fimages%2Fupload%2F08_01_rep_drugtx_ac-ps.pdf&usg=AFQjCNELoKrtA7QE7dvo1rCzfBExa1YzMQ)
- Knudsen, H. K., Abraham, A. J., & Roman, P. M. (2011). Adoption and implementation of medications in addiction treatment programs. *Journal of Addiction Medicine*, 5(1), 21–27. <http://doi.org/10.1097/ADM.0b013e3181d41ddb>

- Kroenke, K., & Spitzer, R. L. (2002). The PHQ-9: A new depression diagnostic and severity measure. *Psychiatric Annals*, 32(9), 509-515. doi:10.3928/0048-5713-20020901-06
- Krupitsky, E., Nunes, E. V., Ling, W., Illeperuma, A., Gastfriend, D. R., & Silverman, B. L. (2011). Injectable extended-release naltrexone for opioid dependence. *The Lancet*, 378(9792), 665-665. doi:10.1016/S0140-6736(11)61331-7
- Lapham, S. C., & McMillan, G. P. (2011). Open-label pilot study of extended-release naltrexone to reduce drinking and driving among repeat offenders. *Journal of Addiction Medicine*, 5(3), 163-169. doi: 10.1097/ADM.0b013e3181eb3b89
- Labrecque, R. M., Smith, P., Lovins, B. K., & Latessa, E. J. (2014). The importance of reassessment: How changes in the LSI-R risk score can improve the prediction of recidivism. *Journal of Offender Rehabilitation*, 53(2), 116-128. doi:10.1080/10509674.2013.868389
- Lee, J. D., Friedmann, P. D., Boney, T. Y., Hoskinson, J., Randall A, McDonald, R., Gordon, M., . O'Brien, C. P. (2015a). Extended-release naltrexone to prevent relapse among opioid dependent, criminal justice system involved adults: Rationale and design of a randomized controlled effectiveness trial. *Contemporary Clinical Trials*, 41, 110-117. doi:10.1016/j.cct.2015.01.005
- Lee, J. D., McDonald, R., Grossman, E., McNeely, J., Laska, E., Rotrosen, J., & Gourevitch, M. N. (2015b). Opioid treatment at release from jail using extended-release naltrexone: A pilot proof-of-concept randomized effectiveness trial. *Addiction*, 110(6), 1008-1014. doi: 10.1111/add.12894

Marlowe, D. B., Festinger, D. S., Lee, P. A., Dugosh, K. L., & Benasutti, K. M. (2006).

Matching judicial supervision to clients' risk status in drug court. *Crime & Delinquency*, 52(1), 52-76. doi:10.1177/0011128705281746

Martin, S., & Colt, S. (2009). *The cost of crime: Could the state reduce future crime and save money by expanding education and treatment programs?* Institute of Social and Economic Research, University of Alaska Anchorage.

McDowell Group, Inc. (2012). *The economic costs of alcohol and other drug abuse in Alaska, 2012 update*. Report prepared for Alaska Mental Health Board & Advisory Board on Alcoholism and Drug Abuse. Retrieved from [http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&cad=rja&uact=8&ved=0ahUKEwir24PYw87JAhUJ6mMKHejbB6wQFgg4MAQ&url=http%3A%2F%2Fdhss.alaska.gov%2Fabada%2FDocuments%2Fpdf%2FEconomicCostofAlcoholandDrugAbuse2012.pdf&usg=AFQjCNGSuxG3FKF\\_5FikljeADftvX5OQBw](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&cad=rja&uact=8&ved=0ahUKEwir24PYw87JAhUJ6mMKHejbB6wQFgg4MAQ&url=http%3A%2F%2Fdhss.alaska.gov%2Fabada%2FDocuments%2Fpdf%2FEconomicCostofAlcoholandDrugAbuse2012.pdf&usg=AFQjCNGSuxG3FKF_5FikljeADftvX5OQBw)

Melnyk, B. M., & Fineout-Overholt, E. (2015). Ethical considerations for evidence implementation and evidence generation. D.P. O'Mathúna (Ed.), *Evidence-based practice in nursing & healthcare* (pp. 515-536). Philadelphia: Wolters Kluwer.

Michie, S., van Stralen, M. M., & West, R. (2011). The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science : IS*, 6, 42. <http://doi.org/10.1186/1748-5908-6-42>

Miller, N. (2013). *RSAT training tool: Medication assisted treatment (MAT) for offender populations*. Retrieved from <http://www.rsat-tta.com/Files/Trainings/FinalMAT>

Moran, K., Burson, R., & Conrad, D. (2014). *The doctor of nursing practice scholarly project*. Burlington, MA: Jones & Bartlett Learning.

Multi-Health Systems, Inc. (2015). Level of service inventory-revised. Retrieved from

<http://www.mhs.com/product.aspx?gr=saf&id=overview&prod=lsi-r>

National Association of Drug Court Professionals. (2013). *Adult Drug Court Best Practice*

*Standards Volume 1*. Retrieved from

<http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwiq-ObmwNzJAhUCwmMKHSF1DXkQFggdMAA&url=http%3A%2F%2Fwww.nadcp.org%2Fsites%2Fdefault%2Ffiles%2Fnadcp%2FAdultDrugCourtBestPracticeStandards.pdf&usg=AFQjCNEYW6iI9KR71OT1RGrchTOkeYBz3Q>

National Association of Drug Court Professionals. (n.d.). *History: Justice professionals pursue a*

*vision*. Retrieved from <http://www.nadcp.org/learn/what-are-drug-courts/drug-court-history>

National Center on Addiction and Substance Abuse at Columbia University. (2010). *Behind*

*bars II: Substance abuse an America's prison population*. Retrieved from

<http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0CCUQFjABahUKEwiFl8fk9JbJAhVO-mMKHcWeDBA&url=http%3A%2F%2Fwww.casacolumbia.org%2Fdownload%2Ffile%2Ffid%2F487&usg=AFQjCNEIDbYt66MG3EO7JVAbFTzgBUWkWg>

National Center on Addiction and Substance Abuse at Columbia University. (2012). *Addiction*

*medicine: Closing the gap between science and practice*. Retrieved from

<http://www.casacolumbia.org/download/file/fid/1177>

National Institute on Alcohol Use and Alcoholism. (2005). *Helping patients who drink too much:*

*A clinician's guide*. Retrieved from

[http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians\\_guide.htm](http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians_guide.htm)

National Institute on Drug Abuse. (2009). *DrugFacts: Treatment approaches for drug addiction*.

Retrieved from <http://www.drugabuse.gov/publications/drugfacts/treatment-approaches-drug-addiction>

National Institute on Drug Abuse. (2012a). *Principles of drug addiction treatment: A research-based guide* (3<sup>rd</sup> ed.) (NIH Publication No. 12–4180). Retrieved from

[https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/podat\\_1.pdf](https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/podat_1.pdf)

National Institute on Drug Abuse. (2012b). *Resource guide: Screening for drug use in general medical settings*. Retrieved from <https://www.drugabuse.gov/publications/resource-guide-screening-drug-use-in-general-medical-settings/nida-quick-screen>

National Institutes of Health. (2013). *Addiction and the criminal justice system*. Retrieved from <http://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=22>

National Institute of Justice. (2014). *Recidivism*. Retrieved from

<http://www.nij.gov/topics/corrections/recidivism/pages/welcome.aspx>

New York University School of Medicine. (2010). Extended-release naltrexone for opioid relapse prevention following release from jail. Retrieved from

<https://clinicaltrials.gov/ct2/show/NCT01180647?term=naltrexone+and+prison&rank=2>

(Identification No. NCT01180647)

New York University School of Medicine. (2013). Extended-release naltrexone opioid treatment at jail re-entry (XOR). Retrieved from

<https://clinicaltrials.gov/ct2/show/NCT01999946?term=naltrexone+and+prison&rank=1>

(Identification No. NCT01999946)

Office of National Drug Control Policy. (2012). *Medication-assisted treatment for opioid addiction*. Retrieved from

[https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwit6qzJ1c7JAhUBwmMKHe5gBZkQFggcMAA&url=https%3A%2F%2Fwww.whitehouse.gov%2Fsites%2Fdefault%2Ffiles%2Fondcp%2Frecovery%2Fmedication\\_assisted\\_treatment\\_9-21-20121.pdf&usg=AFQjCNHAQrjuRNzTMK7Wj04vT1VCISmHOA&bvm=bv.109395566,d.cGc](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwit6qzJ1c7JAhUBwmMKHe5gBZkQFggcMAA&url=https%3A%2F%2Fwww.whitehouse.gov%2Fsites%2Fdefault%2Ffiles%2Fondcp%2Frecovery%2Fmedication_assisted_treatment_9-21-20121.pdf&usg=AFQjCNHAQrjuRNzTMK7Wj04vT1VCISmHOA&bvm=bv.109395566,d.cGc)

Office of National Drug Control Policy. (2015). *National Drug Control Strategy*. Retrieved from

[https://www.whitehouse.gov//sites/default/files/ondcp/policy-and-research/2015\\_national\\_drug\\_control\\_strategy\\_0.pdf](https://www.whitehouse.gov//sites/default/files/ondcp/policy-and-research/2015_national_drug_control_strategy_0.pdf)

Office of National Drug Control Policy. (n.d.). *Substance abuse and the affordable care act*.

Retrieved from <https://www.whitehouse.gov/ondcp/healthcare>

Oser, C. B., Knudsen, H. K., Staton-Tindall, M., Taxman, F., & Leukefeld, C. (2009).

Organizational-level correlates of the provision of detoxification services and medication-based treatments for substance abuse in correctional institutions. *Drug and Alcohol Dependence*, 103(Supplement 1), S73-S81.

doi:10.1016/j.drugalcdep.2008.11.005

Office of National Drug Control Policy. (n.d.). Therapeutic courts. Retrieved from

<http://www.partnersforprogressak.org/partnering-with-the-alaska-court-system/>

Partners for Progress. (n.d.). *Partners reentry center*. Retrieved from

<http://www.partnersforprogressak.org/partners-reentry-center/>

Phillips, L. A. (2010). Substance abuse and prison recidivism: Themes from qualitative

interviews. *Journal of Addictions & Offender Counseling*, 31(1), 10-24. Retrieved from

<http://search.proquest.com.proxy.consortiumlibrary.org/docview/763365613?accountid=14473>

Rhode Island Hospital. (2012). *Pre-release VIVITROL for opioid dependent inmates*. Retrieved from

<https://clinicaltrials.gov/ct2/show/NCT01563718?term=naltrexone+and+prison&rank=3>

(Identification No. NCT01563718)

S. 91, 29th Gen. Assem., Reg. Sess. (Alaska 2015-2016).

Smith, P. C., Schmidt, S. M., Allensworth-Davies, D., & Saitz, R. (2009). Primary care

validation of a single-question alcohol screening test. *Journal of General Internal*

*Medicine*, 24(7), 783-788. doi:10.1007/s11606-009-0928-6

Substance Abuse and Mental Health Services Administration. (2012). *An introduction to extended-release injectable naltrexone for the treatment of people with opioid*

*dependence* (HHS Publication No. 12-4682). Retrieved from

<https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwiCpe6eptzJAhVX4mMKHaGrCmQQFggdMAA&url=https%3A%2F%2Fstore.samhsa.gov%2Fshin%2Fcontent%2FSMA12-4682%2FSMA12-4682.pdf&usg=AFQjCNHfBkosxuGf0yFoCigMdgvitY4tTw>

- Substance Abuse and Mental Health Services Administration. (2015a). *Coding for screening and brief intervention reimbursement*. Retrieved from <http://www.samhsa.gov/sbirt/coding-reimbursement>
- Substance Abuse and Mental Health Services Administration. (2015b). *Medication-assisted treatment*. Retrieved from <http://www.samhsa.gov/medication-assisted-treatment>
- Substance Abuse and Mental Health Services Administration. (2016a). *Medication-assisted treatment of opioid use disorder: Pocket guide*. Retrieved from <http://store.samhsa.gov/product/Medication-Assisted-Treatment-of-Opioid-Use-Disorder-Pocket-Guide/SMA16-4892PG>
- Substance Abuse and Mental Health Services Administration. (2016b). *Screening, brief intervention, and referral to treatment (SBIRT)*. Retrieved from <http://www.samhsa.gov/sbirt>
- State of Alaska. (2015a). *Alcohol use*. Retrieved from [http://ibis.dhss.alaska.gov/topic/risk\\_resiliency/behaviors/Alcohol.html](http://ibis.dhss.alaska.gov/topic/risk_resiliency/behaviors/Alcohol.html)
- State of Alaska. (2015b). *The healthy Alaska plan: a catalyst for reform*. Retrieved from [http://dhss.alaska.gov/HealthyAlaska/Documents/Healthy\\_Alaska\\_Plan\\_FINAL.pdf](http://dhss.alaska.gov/HealthyAlaska/Documents/Healthy_Alaska_Plan_FINAL.pdf)
- Sullivan, J. T., Sykora, K., Schneiderman, J., Naranjo, C. A., & Sellers, E. M. (1989). Assessment of alcohol withdrawal: The revised Clinical Institute Withdrawal Assessment for Alcohol scale (CIWA-Ar). *British Journal of Addiction* 84:1353-1357.
- Surgeon General of the United States. (n.d.). *Turn the tide Rx*. Retrieved from <http://turnthetiderx.org/#>
- Telidevara, S. (2010). *Essays on recidivism* (Order No. 3423534). Available from ProQuest Dissertations & Theses Global. (759413499). Retrieved from



<http://search.proquest.com.proxy.consortiumlibrary.org/docview/759413499?accountid=14473>

University of Alaska Anchorage. (2012). *Institutional review board (IRB)*. Retrieved from <https://www.uaa.alaska.edu/research/ric/irb/>

University of California, Los Angeles. (2014). *Injectable pharmacotherapy for opioid use disorders (IPOD)*. Retrieved from <https://clinicaltrials.gov/ct2/show/NCT02110264?term=naltrexone+and+prison&rank=9>  
(Identification No. NCT02110264)

University of Oslo. (2012). *Naltrexone vs buprenorphine-naloxone for opioid dependence in Norway (NTX-SBX)*. Retrieved from <https://clinicaltrials.gov/ct2/show/NCT01717963?term=naltrexone+and+prison&rank=8>  
(Identification No. NCT01717963)

University of Pennsylvania. (2015). *Outcomes of opioid addicted prisoners with extended-release injectable naltrexone (OAPXRNTX)*. Retrieved from <https://clinicaltrials.gov/ct2/show/NCT02617628?term=naltrexone+and+prison&rank=6>  
(Identification No. NCT02617628)

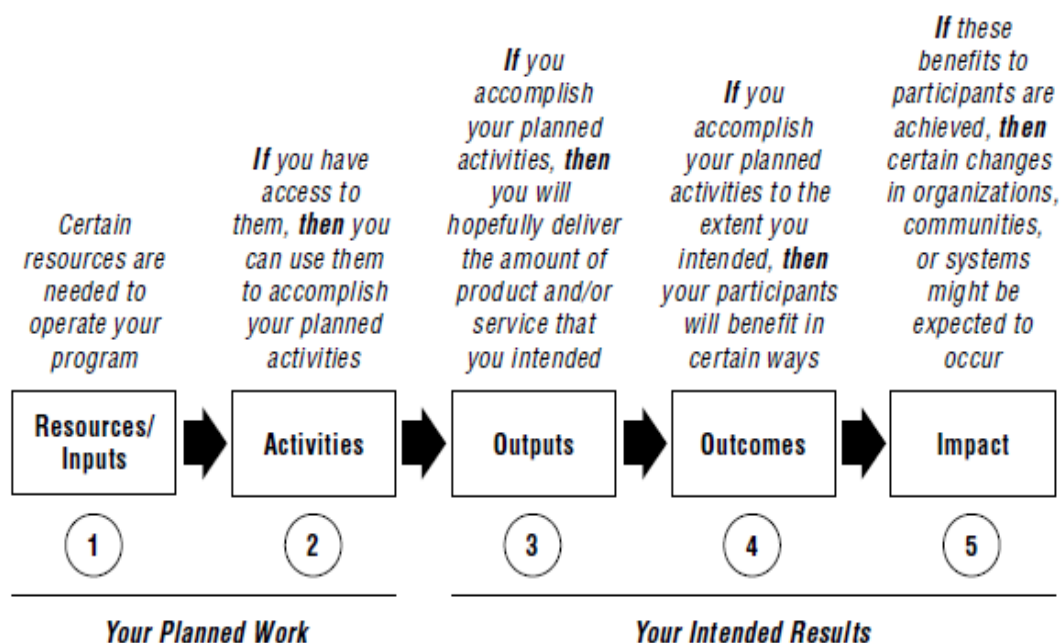
U.S. Department of Health and Human Services Protection of Human Subjects, 45 C.F.R. 46 (2009).

U.S. Department of Health and Human Services Office for Human Research Protections. (2003). *OHRP guidance on the involvement of prisoners in research*. Retrieved from <http://www.hhs.gov/ohrp/policy/prisoner.html>

- Visher, C. A., Winterfield, L., & Coggeshall, M. B. (2005). Ex-offender employment programs and recidivism: A meta-analysis. *Journal of Experimental Criminology*, 1(3), 295-316. doi:10.1007/s11292-005-8127-x
- Wesson, D. R., & Ling, W. (2003). The clinical opiate withdrawal scale (COWS). *Journal of Psychoactive Drugs*, 35(2), 253. doi:10.1080/02791072.2003.10400007
- The White House. (2016a). *Fact sheet: Obama administration announces prescription opioid and heroin epidemic awareness week*. Retrieved from <https://www.whitehouse.gov/the-press-office/2016/09/19/fact-sheet-obama-administration-announces-prescription-opioid-and-heroin>
- The White House. (2016b). *Fact sheet: President Obama proposes \$1.1 billion in new funding to address the prescription opioid abuse and heroin use epidemic*. Retrieved from <https://www.whitehouse.gov/the-press-office/2016/02/02/president-obama-proposes-11-billion-new-funding-address-prescription>
- W. K. Kellogg Foundation. (2004). *Logic model development guide*. Retrieved from [http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwj\\_94rai6bKAhUHxmMKHVzSBqUQFgggMAA&url=http%3A%2F%2Fwww.smartgivers.org%2Fuploads%2Flogicmodelguidepdf.pdf&usg=AFQjCNFyaxM47yb1OuELUvcMLm3rg6aTPw](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwj_94rai6bKAhUHxmMKHVzSBqUQFgggMAA&url=http%3A%2F%2Fwww.smartgivers.org%2Fuploads%2Flogicmodelguidepdf.pdf&usg=AFQjCNFyaxM47yb1OuELUvcMLm3rg6aTPw)

## Appendix A

### Logic Model



W.K. Kellogg Foundation. (2004). Logic model development guide. Retrieved from

[http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwj\\_94rai6bKAhUHxmMKHVzSBqUQFgggMAA&url=http%3A%2F%2Fwww.smartgivers.org%2Fuploads%2Flogicmodelguidepdf.pdf&usg=AFQjCNFyaxM47yb1OuELUvcMLm3rg6aTPw](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwj_94rai6bKAhUHxmMKHVzSBqUQFgggMAA&url=http%3A%2F%2Fwww.smartgivers.org%2Fuploads%2Flogicmodelguidepdf.pdf&usg=AFQjCNFyaxM47yb1OuELUvcMLm3rg6aTPw)

## Appendix B

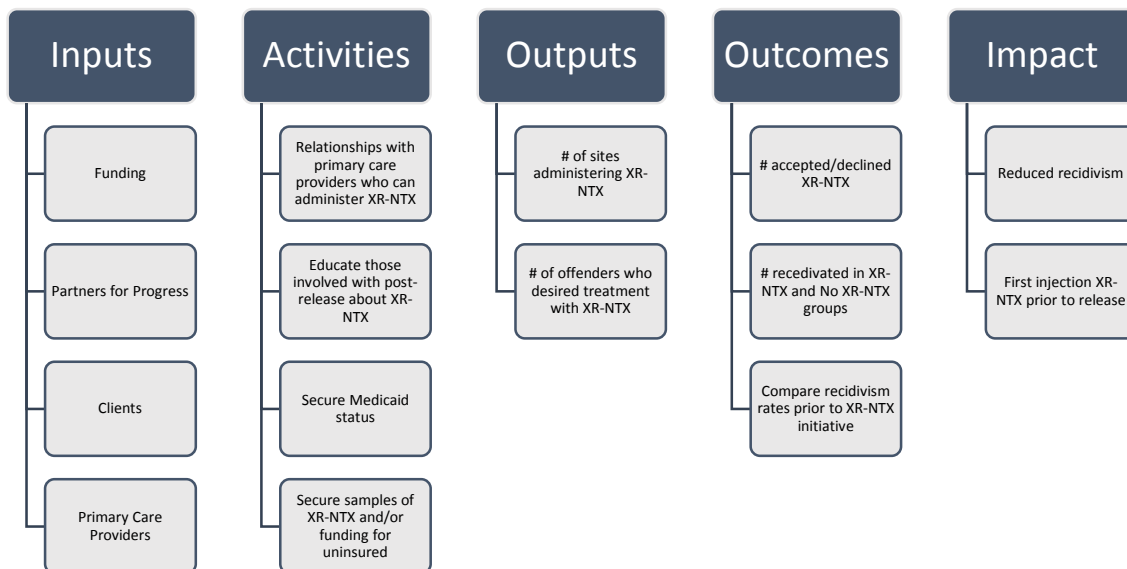
### Logic Model Early Access Extended-Release Injectable Naltrexone (XR-NTX)

#### Assumptions:

- (1) Recidivism affects our community, and partnerships formed within our community will help improve recidivism.
- (2) Expanding Medicaid in the State of Alaska will improve access to care and substance abuse treatment.
- (3) Shifting revenues to provide for early access to XR-NTX will improve health outcomes and reduce recidivism.
- (4) Our community can unite to shape policy at local and state levels as it pertains to recidivism.

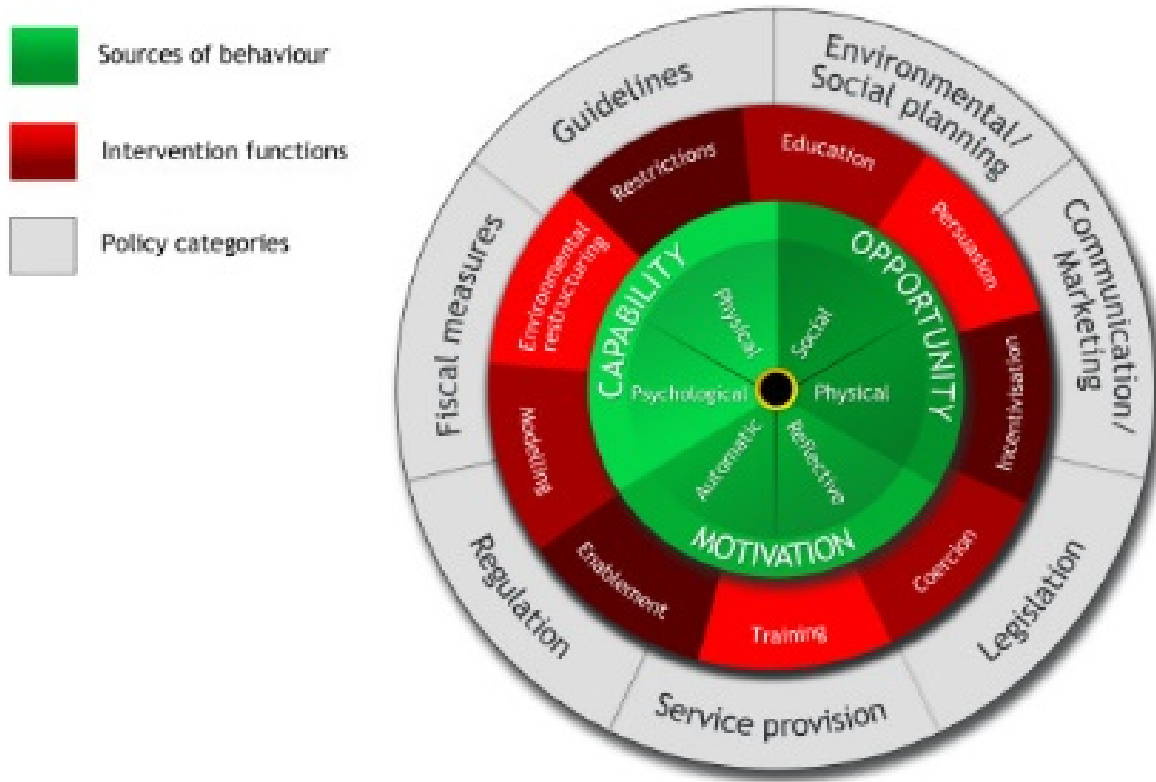
**Vision and mission:** Facilitate early access to XR-NTX for returning offenders while educating healthcare providers about the use of XR-NTX to aid substance abuse treatment.

**Goal:** Reduce recidivism rate.



## Appendix C

### Behavioural Change Wheel



Michie, S., van Stralen, M. M., & West, R. (2011). The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science* : IS, 6, 42. <http://doi.org/10.1186/1748-5908-6-42>

## Appendix D

### Partners for Progress Letter of Support



417 Barrow St.  
Anchorage, AK 99501  
Ph: (907) 272-1192  
Fax: (907) 272-1194  
[www.partnersforprogressak.org](http://www.partnersforprogressak.org)

---

February 10, 2016

Partners for Progress  
417 Barrow Street  
Anchorage, AK 99501  
907-272-1192

Jyll Green  
Nurse Practitioner, DNP Candidate University of Alaska Anchorage  
2105 E 88<sup>th</sup> Avenue  
Anchorage, Alaska 99507

Dear Ms. Green:

Partners for Progress appreciates the opportunity to collaborate in your initiative to provide access to extended release injectable naltrexone (Vivitrol) for recently released prisoners. Our clients are offered Vivitrol on a volunteer basis after being educated on their options for treatment of prior substance abuse. This is a valuable program that will hopefully help released prisoners have success in their community.

Partners for Progress already tracks data on participants in regards to participation in our programs. We are able to provide the following retrospective, de-identified data:

- Descriptive statistics including age, race, ethnicity, reason for incarceration, length of incarceration
- LSI-R scores
- Total numbers served in Wellness Court and in Partners Reentry Center
- Numbers who accepted or declined Vivitrol
- Numbers who received Vivitrol and recidivated
- Numbers who declined Vivitrol and recidivated
- Number of Vivitrol injections received

Partners' goal is to promote prisoner success in the community and reduce recidivism. We would like to participate in generating evidence that will best support that goal.

Sincerely,

Doreen Schenkenberger  
Executive Director

Cathleen McLaughlin, MBA, JD  
Reentry Center Director

## Appendix E

### IRB Determination Letter



#### INSTITUTIONAL REVIEW BOARD REQUEST FOR DETERMINATION OF HUMAN SUBJECTS RESEARCH

All research conducted by University of Alaska Anchorage faculty, staff, or students, which involves human subjects must be reviewed by the Institutional Review Board (IRB). To determine if your project involves human subjects or is research under UAA IRB definitions, complete this form and send it to the UAA Research Compliance Officer, [simumaw@uaa.alaska.edu](mailto:simumaw@uaa.alaska.edu). For help, contact the Office of Research Integrity & Compliance (ORIC): (907) 786-1099.

Consider your activity (research project, thesis, study, task, assignment) and the data (information) you, a member of your research team, or a collaborator, plan to collect, when responding to these questions.

Activity Examples: surveys, questionnaires, focus groups, interviews passive observation of public behavior (in physical or online environments, including social media) experiments using electronic equipment or gaming techniques the use of instruments or devices, including phones, to collect or monitor or influence behavior diet, nutrition studies, or taste tests physical or biomedical procedures, such as imaging, scanning, blood collection, anthropomorphic procedures studies examining individuals' responses to manipulation of their physical or online environment studies examining effectiveness of educational tools or curricula pilot studies and other preliminary studies any other activity that involves observation of, or interaction with, individuals to gather information for research.

Enter a response for each question, complete Section B on Page 2 and send to [simumaw@uaa.alaska.edu](mailto:simumaw@uaa.alaska.edu) Yes/No Not sure

Is all of the data (information) being obtained about deceased people? (If No, skip the next question and go to RD1) NO

In addition to information about the deceased people, are you also collecting information from living persons about their recollections of the deceased people? (If No, stop here and go to RD 2)

RD1) Does your project only involve existing data, information, documents, or samples that you will obtain from a publicly available source that does not require permission to access the data? (If Yes, stop here and go to RD2.) NO

Does a funding source (federal, state, or local), either directly (direct funder) or indirectly (secondary, or pass-through funder) require IRB review? (If Yes, stop here and go to RD3) NO

Is any of the data (information) being obtained about individuals who are, or could be, living now? NO

Is any of the data (information) being obtained, directly or indirectly, from living individuals?  
NO

Are you observing people, directly or indirectly, to collect your information? NO

Are you interacting (face-to-face, through telephone, electronic media or documents) with people? NO

Is the data collected by intervening (taking measurements, samples, images) with people, or observing an intervention carried out by another person? NO

Does the data/information you are collecting only center on things, quantities, or other questions about what item, process, or procedure is used? (If Yes, stop here and go to RD2) YES

Does the data/information you are collecting include the opinions, characteristics, or behavior of individuals?

Does the data/information you are collecting include any information that could identify the individuals?

Does the data/information you are using to recruit people for your project include any information that could identify the individual?

During the process of collecting data, will you or any research team member, be able to identify the individuals?

Will the data or information you are collecting examine, for example, the function of culture, expression of gender, or political views of members of the population in the study?

Could the results of this evaluation be used to make a general conclusion about the data/information you will collect?

Is this evaluation connected to individual or group outcomes?

Could the results of this evaluation impact the future use of similar programs, services, or public policy?

Can this evaluation affect the development or implementation of other programs of a similar nature?

#### INSTITUTIONAL REVIEW BOARD REQUEST FOR DETERMINATION OF HUMAN SUBJECTS RESEARCH

If you answered Not Sure for any question, briefly explain why you are uncertain.

This project is about implementing access to the injectable medication Vivitrol (XR-NTX) for recently released prisoners. We are



evaluating the success of XR-NTX in reducing recidivism in Alaska. There is no focus on the individual receiving the medication. Participants self-selected to receive XR-NTX as part of their treatment program and community re-entry post incarceration.

RD2 – Your work is most likely not human subject research and you do not need to complete the rest of the first section. Complete Section B and return the Request for IRB Determination form for a final confirmation.

RD3 – Your work must be reviewed by the IRB. Go to IRBNet and complete a UAA IRB Proposal and all additional documents for IRB review.

Section B – Instructions, tab to each box and complete the information.

Name: Jyll Green

Today's Date: February 19, 2016

Affiliation with UAA (If this project will be used for class credit, complete the next two lines. If not, skip to Faculty/Staff):

Student Level: Choose an item.DNP -FNP Course Number: Subject-CourseND A696a

Faculty Advisor: Department:  
Dr. Lisa Jackson School of Nursing

Faculty or Staff: College or School: University of Alaska Anchorage Enter here  
Department:Enter here

Center, Program, or Institute: Click here to enter.

Project Title: Reducing Recidivism in Alaska through Access to Extended-Release Injectable Naltrexone. Reducing Recidivism in Alaska through Access to Extended Release Injectable Naltrexone

Project Description: This Quality Improvement/Access to Care initiative will facilitate early access to XR-NTX for returning prisoners by educating healthcare providers about the use of XR-NTX to aid substance abuse treatment. The goal is to reduce the rate of recidivism in Alaska. Partners for Progress (PFP) including therapeutic courts and Partners Reentry Center, their clients, and local primary care providers all contribute to the effort of the initiative. Increasing the number of sites willing to administer XR-NTX on an urgent basis, along with the number of offenders who chose to receive XR-NTX and do not recidivate, will show success of this program. Retrospective de-identified aggregate data will be provided by Partners for Progress to the project manager including: percentage of offenders who accepted XR-NTX, percentage of offenders who did not accept XR-NTX, percentage of offenders who recidivated

and accepted XR-NTX, percentage of offenders who recidivated and did not accept XR-NTX. Using the aggregate data obtained through PFP, the effectiveness of the initiative to facilitate early access to XR-NTX and the reduction in recidivism can be measured. Although recently released prisoners is a vulnerable population, only aggregate data will be evaluated. Education and treatment of alcohol and drug addiction is within the scope of the project manager's professional practice.

Population: Recently released prisoners who elected to receive XR-NTX or declined.

Plan: I will not be interacting directly with any participants on whom data has been collected by a third party, Partners for Progress.

Partners will be providing de-identified group statistics to evaluate the effectiveness of implementing early access to XR-NTX upon release from incarceration and its effects on recidivism rates.

For Office of Research Integrity & Compliance Use Only

Final Determination: HSR   Not HSR

Statement of Findings: What questions, not whom questions, analysis of rate changes pre & post training.

**Appendix F****XR-NTX Patient Counseling Checklist****PATIENT COUNSELING****INFORMATION**

Physicians should include the following issues in discussions with patients for whom they prescribe VIVITROL. Please ensure that each patient is given a copy of the FDA-Approved Medication Guide:

- ☐ Advise patients that if they previously used opioids, they may be more sensitive to lower doses of opioids and at risk of accidental overdose should they use opioids when their next dose is due, if they miss a dose, or after VIVITROL treatment is discontinued. It is important that patients inform family members and the people closest to the patient of this increased sensitivity to opioids and the risk of overdose.
- ☐ Advise patients that because VIVITROL can block the effects of opioids, patients will not perceive any effect if they attempt to self-administer heroin or any other opioid drug in small doses while on VIVITROL. Further, emphasize that administration of large doses of heroin or any other opioid to try to bypass the blockade and get high while on VIVITROL may lead to serious injury, coma, or death.
- ☐ Patients on VIVITROL may not experience the expected effects from opioid-containing analgesic, antidiarrheal, or antitussive medications.
- ☐ Advise patients that a reaction at the site of VIVITROL injection may occur. Reactions include pain, tenderness, induration, swelling, erythema, bruising, or pruritus. Serious injection site reactions including necrosis may occur. Some of these injection site reactions have required surgery. Patients should receive their injection from a healthcare provider qualified to administer the injection. Patients should be advised to seek medical attention for worsening skin reactions.
- ☐ Advise patients that they should be off all opioids, including opioid-containing medicines, for a minimum of 7 – 10 days before starting VIVITROL in order to avoid precipitation of opioid withdrawal. Patients transitioning from buprenorphine or methadone may be vulnerable to precipitation of withdrawal symptoms for as long as two weeks. Ensure that patients understand that withdrawal precipitated by administration of an opioid antagonist may be severe enough to require hospitalization if they have not been opioid-free for an adequate period of time, and is different from the experience of spontaneous withdrawal that occurs with discontinuation of opioid in a dependent individual. Advise patients that they

should not take VIVITROL if they have any symptoms of opioid withdrawal. Advise all patients, including those with alcohol dependence, that it is imperative to notify healthcare providers of any recent use of opioids or any history of opioid dependence before starting VIVITROL to avoid precipitation of opioid withdrawal.

- ☐ Advise patients that VIVITROL may cause liver injury. Patients should immediately notify their physician if they develop symptoms and/or signs of liver disease.
- ☐ Advise patients that they may experience depression while taking VIVITROL. It is important that patients inform family members and the people closest to the patient that they are taking VIVITROL and that they should call a doctor right away should they become depressed or experience symptoms of depression.

## PATIENT COUNSELING INFORMATION

- ☐ Advise patients to carry documentation to alert medical personnel to the fact that they are taking VIVITROL (naltrexone for extended-release injectable suspension). This will help to ensure that patients obtain adequate medical treatment in an emergency.
- ☐ Advise patients that VIVITROL may cause an allergic pneumonia. Patients should immediately notify their physician if they develop signs and symptoms of pneumonia, including dyspnea, coughing, or wheezing.
- ☐ Advise patients that they should not take VIVITROL if they are allergic to VIVITROL or any of the microsphere or diluent components.
- ☐ Advise patients that they may experience nausea following the initial injection of VIVITROL. These episodes of nausea tend to be mild and subside within a few days post-injection. Patients are less likely to experience nausea in subsequent injections. Patients should be advised that they may also experience tiredness, headache, vomiting, decreased appetite, painful joints and muscle cramps.
- ☐ Advise patients that because VIVITROL is an intramuscular injection and not an implanted device, once VIVITROL is injected, it is not possible to remove it from the body.
- ☐ Advise patients that VIVITROL has been shown to treat alcohol and opioid dependence only when used as part of a treatment program that includes counseling and support.

- ☐ Advise patients that dizziness may occur with VIVITROL treatment, and they should avoid driving or operating heavy machinery until they have determined how VIVITROL affects them.
- ☐ Advise patients to notify their physician if they:
- become pregnant or intend to become pregnant during treatment with VIVITROL.
  - are breast-feeding.
  - experience respiratory symptoms such as dyspnea, coughing, or wheezing when taking VIVITROL.
  - experience any allergic reactions when taking VIVITROL.
  - experience other unusual or significant side effects while on VIVITROL therapy.
- ☐ Patients should be advised of any other risks and information based on the clinical judgment of their physician.

A patient wallet card or medical alert bracelet can be ordered from: 1-800-848-4876, Option #1.

For more information, see the FDA-approved [Prescribing Information](#) and [Medication Guide](#).

## IMPORTANT SAFETY INFORMATION FOR VIVITROL<sup>®</sup>

(naltrexone for extended-release injectable suspension)

---

## INDICATIONS

VIVITROL is indicated for:

Treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting. Patients should not be actively drinking at the time of initial VIVITROL administration.

Prevention of relapse to opioid dependence, following opioid detoxification.

VIVITROL should be part of a comprehensive management program that includes psychosocial support.

## CONTRAINDICATIONS

VIVITROL is contraindicated in patients:

Receiving opioid analgesics

With current physiologic opioid dependence

In acute opioid withdrawal

Who have failed the naloxone challenge test or have a positive urine screen for opioids

Who have exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent

## WARNINGS/PRECAUTIONS

**Vulnerability to Opioid Overdose:** Because VIVITROL blocks the effects of exogenous opioids for approximately 28 days after administration, patients are likely to have a reduced tolerance to opioids after opioid detoxification. As the blockade dissipates, use of previously tolerated doses of opioids could result in potentially life-threatening opioid intoxication (respiratory compromise or arrest, circulatory collapse, etc). Cases of opioid overdose with fatal outcomes have been reported in patients who used opioids at the end of a dosing interval, after missing a scheduled dose, or after discontinuing treatment. Patients and caregivers should be told of this increased sensitivity to opioids and the risk of overdose.

Any attempt by a patient to overcome the VIVITROL blockade by taking opioids may lead to fatal overdose. Patients should be told of the serious consequences of trying to overcome the opioid blockade.

**Injection Site Reactions:** VIVITROL injections may be followed by pain, tenderness, induration, swelling, erythema, bruising, or pruritus; however, in some cases injection site reactions may be very severe. Injection site reactions not improving may require prompt medical attention, including, in some cases, surgical intervention. Inadvertent subcutaneous/adipose layer injection of VIVITROL may increase the likelihood of severe injection site reactions. Select proper needle size for patient body habitus, and use only the needles provided in the carton. Patients should be informed that any concerning injection site reactions should be brought to the attention of their healthcare provider.

**Precipitation of Opioid Withdrawal:** Withdrawal precipitated by administration of VIVITROL may be severe. Some cases of withdrawal symptoms have been severe enough to require hospitalization and management in the ICU. To prevent precipitated withdrawal, patients, including those being treated for alcohol dependence: Should be opioid-free (including tramadol) for a minimum of 7–10 days before starting VIVITROL.

Patients transitioning from buprenorphine or methadone may be vulnerable to precipitated withdrawal for as long as two weeks.

Patients should be made aware of the risk associated with precipitated withdrawal and be encouraged to give an accurate account of last opioid use.

**Hepatotoxicity:** Cases of hepatitis and clinically significant liver dysfunction have been observed in association with VIVITROL. Warn patients of the risk of hepatic injury; advise them to seek help if experiencing symptoms of acute hepatitis. Discontinue use of VIVITROL in patients who exhibit acute hepatitis symptoms.

**Depression and Suicidality:** Alcohol- and opioid-dependent patients taking VIVITROL should be monitored for depression or suicidal thoughts. Alert families and caregivers to monitor and report the emergence of symptoms of depression or suicidality.

**When Reversal of VIVITROL Blockade is Required for Pain Management:** For VIVITROL patients in emergency situations, suggestions for pain management include regional analgesia or use of non-opioid analgesics. If opioid therapy is required to reverse the VIVITROL blockade, patients should be closely monitored by trained personnel in a setting staffed and equipped for CPR.

**Eosinophilic Pneumonia:** Cases of eosinophilic pneumonia requiring hospitalization have been reported. Warn patients of the risk of eosinophilic pneumonia and to seek medical attention if they develop symptoms of pneumonia.

**Hypersensitivity Reactions:** Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis.

**Intramuscular Injections:** As with any IM injection, VIVITROL should be administered with caution to patients with thrombocytopenia or any coagulation disorder.

## ADVERSE REACTIONS

Serious adverse reactions that may be associated with VIVITROL therapy in clinical use include severe injection site reactions, eosinophilic pneumonia, serious allergic reactions, unintended precipitation of opioid withdrawal, accidental opioid overdose, and depression and suicidality. The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence include nausea, vomiting, injection site reactions (including induration, pruritus, nodules, and swelling), muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders. The adverse events seen most frequently in association with VIVITROL in opioid-dependent patients also include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

Please see Prescribing Information, including Medication Guide. Review the Medication Guide with your patient.



Alkermes. (2016). *Patient counseling information*. Retrieved from

<https://www.vivitrol.com/HCP/VivitrolResources/PatientCounselingChecklist>

## Appendix G

## NIDA Quick Screen V1.0/ NIDA-Modified ASSIST V2.0

NIDA Quick Screen V1.0<sup>1</sup>

Name: ..... Sex ( ) F ( ) M Age.....

Interviewer..... Date ...../...../.....

## Introduction (Please read to patient)

*Hi, I'm \_\_\_\_\_, nice to meet you. If it's okay with you, I'd like to ask you a few questions that will help me give you better medical care. The questions relate to your experience with alcohol, cigarettes, and other drugs. Some of the substances we'll talk about are prescribed by a doctor (like pain medications). But I will only record those if you have taken them for reasons or in doses other than prescribed. I'll also ask you about illicit or illegal drug use—but only to better diagnose and treat you.*

**Instructions:** For each substance, mark in the appropriate column. For example, if the patient has used cocaine monthly in the past year, put a mark in the “Monthly” column in the “illegal drug” row.

NIDA Quick Screen Question:					
In the past year, how often have you used the following?	Never	Once or Twice	Monthly	Weekly	Daily or Almost Daily
Alcohol					
<ul style="list-style-type: none"> <li>For men, 5 or more drinks a day</li> <li>For women, 4 or more drinks a day</li> </ul>					
Tobacco Products					
Prescription Drugs for Non-Medical Reasons					
Illegal Drugs					



- If the patient says “**NO**” for all drugs in the Quick Screen, reinforce abstinence. **Screening is complete.**
- If the patient says “**Yes**” to **one or more days of heavy drinking**, *patient is an at-risk drinker*. Please see NIAAA website “How to Help Patients Who Drink Too Much: A Clinical Approach” [http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians\\_guide.htm](http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians_guide.htm), for information to **Assess, Advise, Assist, and Arrange** help for at risk drinkers or patients with alcohol use disorders
- If patient says “**Yes**” to **use of tobacco**: *Any current tobacco use places a patient at risk. Advise all tobacco users to quit.* For more information on smoking cessation, please see “Helping Smokers Quit: A Guide for Clinicians” <http://www.ahrq.gov/clinic/tobacco/clnhlpsmksqt.htm>
- If the patient says “**Yes**” to **use of illegal drugs or prescription drugs for non-medical reasons**, proceed to **Question 1** of the NIDA-Modified ASSIST.

---

<sup>1</sup> This guide is designed to assist clinicians serving adult patients in screening for drug use. The NIDA Quick Screen was adapted from the single-question screen for drug use in primary care by Saitz et al. (available at <http://archinte.amaassn.org/cgi/reprint/170/13/1155>) and the National Institute on Alcohol Abuse and Alcoholism’s screening question on heavy drinking days (available at [http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians\\_guide.htm](http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians_guide.htm)).

The NIDA-modified ASSIST was adapted from the World Health Organization (WHO) Alcohol, Smoking and Substance Involvement Screening Test (ASSIST), Version 3.0, developed and published by WHO (available at [http://www.who.int/substance\\_abuse/activities/assist\\_v3\\_english.pdf](http://www.who.int/substance_abuse/activities/assist_v3_english.pdf)).

### Questions 1-8 of the NIDA-Modified ASSIST V2.0

---

**Instructions:** Patients may fill in the following form themselves but screening personnel should offer to read the questions aloud in a private setting and complete the form for the patient. To preserve confidentiality, a protective sheet should be placed on top of the questionnaire so it will not be seen by other patients after it is completed but before it is filed in the medical record.

Question 1 of 8, NIDA-Modified ASSIST	Yes	No
<p><b>In your <u>LIFETIME</u>, which of the following substances have you ever used?</b></p> <p><i>*Note for Physicians: For prescription medications, please report nonmedical use only.</i></p>		
<b>a. Cannabis</b> (marijuana, pot, grass, hash, etc.)		
<b>b. Cocaine</b> (coke, crack, etc.)		
<b>c. Prescription stimulants</b> (Ritalin, Concerta, Dexedrine, Adderall, diet pills, etc.)		
<b>d. Methamphetamine</b> (speed, crystal meth, ice, etc.)		
<b>e. Inhalants</b> (nitrous oxide, glue, gas, paint thinner, etc.)		
<b>f. Sedatives or sleeping pills</b> (Valium, Serepax, Ativan, Xanax, Librium, Rohypnol, GHB, etc.)		
<b>g. Hallucinogens</b> (LSD, acid, mushrooms, PCP, Special K, ecstasy, etc.)		
<b>h. Street opioids</b> (heroin, opium, etc.)		
<b>i. Prescription opioids</b> (fentanyl, oxycodone [OxyContin, Percocet], hydrocodone [Vicodin], methadone, buprenorphine, etc.)		
<b>j. Other – specify:</b>		

- Given the patient's response to the Quick Screen, the patient *should not indicate* **“NO”** for all drugs in Question 1. If they do, remind them that their answers to the Quick Screen indicated they used an illegal or prescription drug for nonmedical reasons within the past year and then **repeat Question 1**. If the patient indicates that the drug used is not listed, please mark **‘Yes’** next to ‘Other’ and continue to **Question 2** of the NIDA-Modified ASSIST.
- If the patient says **“Yes”** to any of the drugs, proceed to **Question 2** of the NIDA-Modified ASSIST.

Question 2 of 8, NIDA-Modified ASSIST					
2. <u>In the past three months</u> , how often have you used the substances you mentioned (first drug, second drug, etc)?	Never	Once or Twice	Monthly	Weekly	Daily or Almost Daily
• Cannabis (marijuana, pot, grass, hash, etc.)	0	2	3	4	6
• Cocaine (coke, crack, etc.)	0	2	3	4	6
• Prescription stimulants (Ritalin, Concerta, Dexedrine, Adderall, diet pills, etc.)	0	2	3	4	6
• Methamphetamine (speed, crystal meth, ice, etc.)	0	2	3	4	6
• Inhalants (nitrous oxide, glue, gas, paint thinner, etc.)	0	2	3	4	6
• Sedatives or sleeping pills (Valium, Serepax, Ativan, Librium, Xanax, Rohypnol, GHB, etc.)	0	2	3	4	6
• Hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstasy, etc.)	0	2	3	4	6
• Street opioids (heroin, opium, etc.)	0	2	3	4	6
• Prescription opioids (fentanyl, oxycodone [OxyContin, Percocet], hydrocodone [Vicodin], methadone, buprenorphine, etc.)	0	2	3	4	6
• Other – Specify:	0	2	3	4	6

- For patients who report **“Never”** having used any drug in the past 3 months: **Go to Questions 6-8.**
- For any recent **illicit or nonmedical prescription drug use**, go to **Question 3.**

<b>3. <u>In the past 3 months</u>, how often have you had a strong desire or urge to use (first drug, second drug, etc)?</b>	<b>Never</b>	<b>Once or Twice</b>	<b>Monthly</b>	<b>Weekly</b>	<b>Daily or Almost Daily</b>
<b>a. Cannabis (marijuana, pot, grass, hash, etc.)</b>	0	3	4	5	6
<b>b. Cocaine (coke, crack, etc.)</b>	0	3	4	5	6
<b>c. Prescribed Amphetamine type stimulants (Ritalin, Concerta, Dexedrine, Adderall, diet pills, etc.)</b>	0	3	4	5	6
<b>d. Methamphetamine (speed, crystal meth, ice, etc.)</b>	0	3	4	5	6
<b>e. Inhalants (nitrous oxide, glue, gas, paint thinner, etc.)</b>	0	3	4	5	6
<b>f. Sedatives or sleeping pills (Valium, Serepax, Ativan, Librium, Xanax, Rohypnol, GHB, etc.)</b>	0	3	4	5	6
<b>g. Hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstasy, etc.)</b>	0	3	4	5	6
<b>h. Street Opioids (heroin, opium, etc.)</b>	0	3	4	5	6
<b>i. Prescribed opioids (fentanyl, oxycodone [OxyContin, Percocet], hydrocodone [Vicodin], methadone, buprenorphine, etc.)</b>	0	3	4	5	6
<b>j. Other – Specify:</b>	0	3	4	5	6

4. <u>During the past 3 months</u> , how often has your use of (first drug, second drug, etc) led to health, social, legal or financial problems?	Never	Once or Twice	Monthly	Weekly	Daily or Almost Daily
a. Cannabis (marijuana, pot, grass, hash, etc.)	0	4	5	6	7
b. Cocaine (coke, crack, etc.)	0	4	5	6	7
c. Prescribed Amphetamine type stimulants (Ritalin, Concerta, Dexedrine, Adderall, diet pills, etc.)	0	4	5	6	7
d. Methamphetamine (speed, crystal meth, ice, etc.)	0	4	5	6	7
e. Inhalants (nitrous oxide, glue, gas, paint thinner, etc.)	0	4	5	6	7
f. Sedatives or sleeping pills (Valium, Serepax, Ativan, Librium, Xanax, Rohypnol, GHB, etc.)	0	4	5	6	7
g. Hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstasy, etc.)	0	4	5	6	7
h. Street opioids (heroin, opium, etc.)	0	4	5	6	7
i. Prescribed opioids (fentanyl, oxycodone [OxyContin, Percocet], hydrocodone [Vicodin], methadone, buprenorphine, etc.)	0	4	5	6	7
j. Other – Specify:	0	4	5	6	7

5. <u>During the past 3 months</u> , how often have you failed to do what was normally expected of you because of your use of (first drug, second drug, etc)?	Never	Once or Twice	Monthly	Weekly	Daily or Almost Daily
a. Cannabis (marijuana, pot, grass, hash, etc.)	0	5	6	7	8
b. Cocaine (coke, crack, etc.)	0	5	6	7	8
c. Prescribed Amphetamine type stimulants (Ritalin, Concerta, Dexedrine, Adderall, diet pills, etc.)	0	5	6	7	8
d. Methamphetamine (speed, crystal meth, ice, etc.)	0	5	6	7	8
e. Inhalants (nitrous oxide, glue, gas, paint thinner, etc.)	0	5	6	7	8
f. Sedatives or sleeping pills (Valium, Serepax, Ativan, Librium, Xanax, Rohypnol, GHB, etc.)	0	5	6	7	8
g. Hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstasy, etc.)	0	5	6	7	8
h. Street Opioids (heroin, opium, etc.)	0	5	6	7	8
i. Prescribed opioids (fentanyl, oxycodone [OxyContin, Percocet], hydrocodone [Vicodin], methadone, buprenorphine, etc.)	0	5	6	7	8
j. Other – Specify:	0	5	6	7	8

**Instructions:** Ask Questions 6 & 7 for all substances ever used (i.e., those endorsed in the Question 1).

6. Has a friend or relative or anyone else <u>ever</u> expressed concern about your use of (first drug, second drug, etc)?	No, never	Yes, but not in the past 3 months	Yes, in the past 3 months
a. Cannabis (marijuana, pot, grass, hash, etc.)	0	3	6
b. Cocaine (coke, crack, etc.)	0	3	6
c. Prescribed Amphetamine type stimulants (Ritalin, Concerta, Dexedrine, Adderall, diet pills, etc.)	0	3	6
d. Methamphetamine (speed, crystal meth, ice, etc.)	0	3	6
e. Inhalants (nitrous oxide, glue, gas, paint thinner, etc.)	0	3	6
f. Sedatives or sleeping pills (Valium, Serepax, Xanax, Ativan, Librium, Rohypnol, GHB, etc.)	0	3	6
g. Hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstasy, etc.)	0	3	6
h. Street opioids (heroin, opium, etc.)	0	3	6
i. Prescribed opioids (fentanyl, oxycodone [OxyContin, Percocet], hydrocodone [Vicodin], methadone, buprenorphine, etc.)	0	3	6
j. Other – Specify:	0	3	6

7. Have you ever tried and failed to control, cut down or stop using (first drug, second drug, etc)?	No, never	Yes, but not in the past 3 months	Yes, in the past 3 months
a. Cannabis (marijuana, pot, grass, hash, etc.)	0	3	6
b. Cocaine (coke, crack, etc.)	0	3	6
c. Prescribed Amphetamine type stimulants (Ritalin, Concerta, Dexedrine, Adderall, diet pills, etc.)	0	3	6
d. Methamphetamine (speed, crystal meth, ice, etc.)	0	3	6
e. Inhalants (nitrous oxide, glue, gas, paint thinner, etc.)	0	3	6
f. Sedatives or sleeping pills (Valium, Serepax, Xanax, Ativan, Librium, Rohypnol, GHB, etc.)	0	3	6
g. Hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstasy, etc.)	0	3	6
h. Street opioids (heroin, opium, etc.)	0	3	6
i. Prescribed opioids (fentanyl, oxycodone [OxyContin, Percocet], hydrocodone [Vicodin], methadone, buprenorphine, etc.)	0	3	6
j. Other – Specify:	0	3	6

**Instructions:** Ask Question 8 if the patient endorses any drug that might be injected, including those that might be listed in the other category (e.g., steroids). Circle appropriate response.

8. Have you ever used any drug by injection past 3 (NONMEDICAL USE ONLY)?	No, never	Yes, but not in the past 3 months	Yes, in the past 3 months
---	-----------	-----------------------------------	---------------------------

- Recommend to patients reporting any prior or current intravenous drug use that they get tested for HIV and Hepatitis B/C.
- If patient reports using a drug by injection in the past three months, ask about their pattern of injecting during this period to determine their risk levels and the best

- course of intervention.
- If patient responds that they inject once weekly or less OR fewer than 3 days in a row, provide a brief intervention including a discussions of the risks associated with injecting.
  - If patient responds that they inject more than once per week OR 3 or more days in a row, refer for further assessment.

**Note:** Recommend to patients reporting any current use of alcohol or illicit drugs that they get tested for HIV and other sexually transmitted diseases.

**Tally Sheet for scoring the full NIDA-Modified ASSIST:**

---

**Instructions:** For each substance (labeled a–j), add up the scores received for questions 2–7 above. This is the Substance Involvement (SI) score. Do not include the results from either the Q1 or Q8 (above) in your SI scores.

<b>Substance Involvement Score Total (SI SCORE) a.</b>	
<b>b. Cannabis (marijuana, pot, grass, hash, etc.)</b>	
<b>c. Cocaine (coke, crack, etc.)</b>	
<b>d. Prescription stimulants (Ritalin, Concerta, Dexedrine, Adderall, diet pills, etc.)</b>	
<b>e. Methamphetamine (speed, crystal meth, ice, etc.)</b>	
<b>f. Inhalants (nitrous oxide, glue, gas, paint thinner, etc.)</b>	
<b>g. Sedatives or sleeping pills (Valium, Serepax, Xanax, Ativan, Librium, Rohypnol, GHB, etc.)</b>	
<b>h. Hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstasy, etc.)</b>	
<b>i. Street Opioids (heroin, opium, etc.)</b>	
<b>j. Prescription opioids (fentanyl, hydrocodone [Vicodin], methadone, buprenorphine, etc.)</b>	
<b>Other – Specify:</b>	

**Use the resultant Substance Involvement (SI) Score to identify patient's risk level.**



To determine patient's risk level based on his or her SI score, see the table below:

Level of risk associated with different Substance Involvement Score ranges for Illicit or nonmedical prescription drug use	
0-3	Lower Risk
4-26	Moderate Risk
27+	High Risk

National Institute on Drug Abuse. (2012b). *Resource guide: Screening for drug use in general medical settings*. Retrieved from <https://www.drugabuse.gov/publications/resource-guide-screening-drug-use-in-general-medical-settings/nida-quick-screen>

## Appendix H

## Patient Health Questionnaire-9

## PATIENT HEALTH QUESTIONNAIRE-9

### (PHQ-9)

Over the last 2 weeks, how often have you been  
bothered by any of the following problems? (Use "✓" to  
indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3

---

9. Thoughts that you would be better off dead or of hurting  
yourself in some way

0                      1                      2                      3

---

FOR OFFICE CODING   0   +        +        +       

=Total Score:       

---

If you checked off any problems, how difficult have these problems made it for you to do your work,  
take care of things at home, or get along with other people?

Not difficult  
at all

⑤

Somewhat  
difficult

⑤

Very  
difficult

⑤

Extremely  
difficult

⑤

---

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Kroenke, K., & Spitzer, R. L. (2002). The PHQ-9: A new depression diagnostic and severity  
measure. *Psychiatric Annals*, 32(9), 509-515. doi:10.3928/0048-5713-20020901-06

## Appendix I

### Medication-Assisted Treatment of Opioid Use Disorder: Pocket Guide



Nearly 80 percent of individuals with an opioid use disorder do not receive treatment. In the 2014 National Survey on Drug Use and Health (NSDUH), 435,000 respondents ages 12 or older reported current use of heroin. Nonmedical use of pain relievers continues to be more widespread than heroin use — 4.3 million NSDUH respondents reported nonmedical use of pain relievers in the past month. Medication-assisted treatment (MAT) is an effective response to opioid use disorder. It is the use of medications, in combination with behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders. Individuals receiving MAT often demonstrate dramatic improvement in addiction-related behaviors and psychosocial functioning.

The first barrier to accessing treatment is failure to recognize substance use disorder. Screening, Brief Intervention, and Referral to Treatment (SBIRT) is an approach in which screening is followed up as appropriate with brief intervention to promote healthy behavior change and with referral to treatment for those needing more extensive care. ([www.samhsa.gov/sbirt](http://www.samhsa.gov/sbirt))



Produced by the Substance Abuse and Mental Health Services Administration (SAMHSA).

## Checklist for Prescribing Medication for the Treatment of Opioid Use Disorder

### ✓ Assess the need for treatment

For persons diagnosed with an opioid use disorder, first determine the severity of patient's substance use disorder. Then identify any underlying or co-occurring diseases or conditions, the effect of opioid use on the patient's physical and psychological functioning, and the outcomes of past treatment episodes.

Your assessment should include:

#### A patient history

- Ensure that the assessment includes a medical and psychiatric history, a substance use history, and an evaluation of family and psychosocial supports.
- Access the patient's prescription drug use history through the state's prescription drug monitoring program (PDMP), where available, to detect unreported use of other medications, such as sedative-hypnotics or alcohol, that may interact adversely with the treatment medications.

### TREATMENT OF OPIOID USE DISORDER

3

### TREATMENT OF OPIOID USE DISORDER

4

- A physical examination that focuses on physical findings related to addiction and its complications.
- Laboratory testing to assess recent opioid use and to screen for use of other drugs. Useful tests include a urine drug screen or other toxicology screen, urine test for alcohol (ethyl glucuronide), liver enzymes, serum bilirubin, serum creatinine, as well as tests for hepatitis B and C and HIV.

### ✓ Educate the patient about how the medication works and the associated risks and benefits; obtain informed consent; and educate on overdose prevention.

There is a potential for relapse and overdose on discontinuation of the medication. Patients should be educated about the effects of using opioids and other drugs while taking the prescribed medication and the potential for overdose if opioid use is resumed after tolerance is lost.

### ✓ Evaluate the need for medically managed withdrawal from opioid

Naltrexone patients must first be medically withdrawn from opioids.

✓ **Address co-occurring disorders**

Have an integrated treatment approach to meet the substance use, medical and mental health, and social needs of a patient.

✓ **Integrate pharmacologic and nonpharmacologic therapies**

All medications for the treatment of the opioid use disorder should be prescribed as part of a comprehensive individualized treatment plan that includes counseling and other psychosocial therapies, as well as social support through participation in Narcotics Anonymous and other mutual-help programs.

✓ **Refer patients for higher levels of care, if necessary**

Refer the patient for more intensive or specialized services if office-based treatment with buprenorphine or naltrexone is not effective or the clinician does not have the resources to meet a particular patient's needs. Providers can find programs in their areas or throughout the United States by using SAMHSA's Behavioral Health Treatment Services Locator at [www.findtreatment.samhsa.gov](http://www.findtreatment.samhsa.gov).

TREATMENT OF OPIOID USE DISORDER

6

## Medications Approved in the Treatment of Opioid Use Disorder\*

### ► Frequency of Administration

Extended Release Injectable Naltrexone	Methadone	Buprenorphine
Monthly*	Daily	Daily (also alternative dosing regimen)

### ► Route of Administration

Extended Release Injectable Naltrexone	Methadone	Buprenorphine
Intramuscular (IM) injection into the gluteal muscle by a physician or other health care professional.*	Orally as liquid concentrate, tablet or oral solution of disperse or powder.	Oral tablet or film is dissolved under the tongue.

## ► Who May Prescribe or Dispense

Extended Release Injectable Naltrexone	Methodone	Buprenorphine
Any individual who is licensed to prescribe medicines (e.g., physician, physician assistant, nurse practitioner) may prescribe and/or order administration by qualified staff.	SAMHSA-certified Opioid Treatment Programs dispense methadone for daily administration either on site or, for stable patients, at home.	Physicians must have board certification in addiction medicine or addiction psychiatry and/or complete special training to qualify for the federal waiver to prescribe buprenorphine, but any pharmacy can fill the prescription.  There are no special requirements for staff members who dispense buprenorphine under the supervision of a waived physician.

\*Table highlights some properties of each medication. It does not provide complete information and is not intended as a substitute for the package inserts or other drug reference sources used by clinicians (see [www.drugs.com/druginfo/](http://www.drugs.com/druginfo/) for current package inserts). For patient information about these and other drugs, visit the National Library of Medicine's MedlinePlus ([www.nlm.nih.gov/](http://www.nlm.nih.gov/)). Whether a medication should be prescribed and in what amount are matters to be discussed between an individual and his or her health care provider. The prescribing information provided here is not a substitute for the clinician's judgment, and the National Institutes of Health and SAMHSA accept no liability or responsibility for use of the information in the care of individual patients.

\*Naltrexone hydrochloride tablets (50 mg each) are also available for daily dosing.

## TREATMENT OF OPIOID USE DISORDER

7

## TREATMENT OF OPIOID USE DISORDER

8

## ► Pharmacologic Category

Extended Release Injectable Naltrexone	Methodone	Buprenorphine
<b>Opioid antagonist</b> Naltrexone displaces opioids from receptors to which they have bound. This can precipitate severe, acute withdrawal symptoms if administered in persons who have not completely cleared opioids from their system. Patients who have been treated with extended-release injectable naltrexone will have reduced tolerance to opioids. Subsequent exposure to previously tolerated or even smaller amounts of opioids may result in overdose.	<b>Opioid agonist</b> Patients starting methadone should be educated about the risk of overdose during induction onto methadone, if relapse occurs, or substances such as benzodiazepines or alcohol are consumed. During induction, a dose that seems initially inadequate can be toxic a few days later because of accumulation in body tissues. For guidance on methadone dosing for all phases of MAT consult TIP 43 ( <a href="https://store.samhsa.gov/product/TIP-43-Medication-Assisted-Treatment-for-Substance-Use-Disorders">https://store.samhsa.gov/product/TIP-43-Medication-Assisted-Treatment-for-</a>	<b>Opioid partial agonist</b> Buprenorphine's partial agonist effect relieves withdrawal symptoms resulting from cessation of opioids. This same property will induce a syndrome of acute withdrawal in the presence of long-acting opioids or sufficient amounts of receptor-bound full agonists. Naltrexone, an opioid antagonist, is sometimes added to buprenorphine to make the product less likely to be abused by injection.

## ► Clinical Uses/Ideal Candidates

Extended Release Injectable Naltrexone	Methodone	Buprenorphine
Prevention of relapse to opioid use disorder following opioid detoxification studies suggest benefits for patients who are experiencing increased stress or other relapse risks (e.g., visiting places of previous drug use, loss of spouse, loss of job). Appropriate for patients who have been detoxified from opioids and who are being treated for a co-occurring alcohol use disorder. Extended-release naltrexone should be part of a comprehensive management program that includes psychosocial support. Other good candidates include persons with a short or less severe addiction history or who must demonstrate to professional licensing boards or criminal justice officials that their risk of opioid use is low.	Detoxification and maintenance treatment of opioid addiction.  Patients who are motivated to adhere to the treatment plan and who have no contraindications to methadone therapy.  Methadone should be part of a comprehensive management program that includes psychosocial support.	Treatment of opioid dependence.  Patients who are motivated to adhere to the treatment plan and who have no contraindications to buprenorphine therapy.  Buprenorphine should be part of a comprehensive management program that includes psychosocial support.

## TREATMENT OF OPIOID USE DISORDER

9

► **Contraindications**

Extended Release Injectable Naltrexone	Metadone	Buprenorphine
<p>Contraindicated in patients receiving long-term opioid therapy.</p> <p>Contraindicated in patients who are engaged in current opioid use (as indicated by self-report or a positive urine drug screen) or who are on buprenorphine or methadone maintenance therapy, as well as in those currently undergoing opioid withdrawal.</p> <p>Contraindicated in patients with a history of sensitivity to polyethylene glycol, carboxymethylcellulose, or any components of the diluent.</p> <p>Should not be given to patients whose body mass precludes IM injection with the 2-inch needle provided; inadvertent subcutaneous injection may cause a severe injection site reaction.</p> <p>Should not be given to anyone allergic to naltrexone.</p>	<p>Contraindicated in patients who are hypersensitive to methadone hydrochloride or any other ingredient in methadone hydrochloride tablets, diskiets, powder or liquid concentrate.</p> <p>Contraindicated in patients with respiratory depression (in the absence of resuscitative equipment) or in unmonitored settings) and in patients with acute bronchial asthma or hypercarbia.</p> <p>Contraindicated in any patient who has or is suspected of having a paralytic ileus.</p>	<p>Contraindicated in patients who are hypersensitive to buprenorphine or naltrexone.</p>

► **Warnings**

Extended Release Injectable Naltrexone	Metadone	Buprenorphine
<p>Use with caution in patients with active liver disease, moderate to severe renal impairment, and women of childbearing age.</p> <p>Discontinue in the event of symptoms or signs of acute hepatitis.</p> <p>As with any IM injection, extended-release injectable naltrexone should be used with caution in patients with thrombocytopenia or any coagulation disorder (e.g., hemophilia, severe hepatic failure); such patients should be closely monitored for 24 hours after naltrexone is administered.</p> <p>Patients may become sensitive to lower doses of opioids after treatment with extended-release injectable naltrexone. This could result in potentially life-threatening opioid intoxication and overdose if previously tolerated larger doses are administered.</p> <p>Clinicians should warn patients that overdose may result from trying to overcome the opioid blockade effects of naltrexone.</p>	<p>Methadone should be used with caution in elderly and debilitated patients; patients with head injury or increased intracranial pressure; patients who are known to be sensitive to central nervous system depressants, such as those with cardiovascular, pulmonary, renal, or hepatic disease; and patients with comorbid conditions or concomitant medications that may predispose to dysrhythmia or reduced ventilatory drive.</p> <p>Methadone should be administered with caution to patients already at risk for development of prolonged QT interval or serious arrhythmia.</p> <p>The label includes a warning about somnolence that may preclude driving or operating equipment.</p>	<p>Caution is required in prescribing buprenorphine to patients with polysubstance use and those who have severe hepatic impairment, compromised respiratory function, or head injury.</p> <p>Significant respiratory depression and death have occurred in association with buprenorphine, particularly administered intravenously or in combination with benzodiazepines or other central nervous system depressants (including alcohol).</p> <p>Buprenorphine may precipitate withdrawal if initiated before patient is in opioid withdrawal, particularly in patients being transferred from methadone.</p> <p>The label includes a warning about somnolence that may preclude driving or operating equipment.</p>



## ► Use in Pregnant and Postpartum Women

Extended Release Injectable Naltrexone	Methadone	Buprenorphine
<p><b>Pregnancy:</b> FDA pregnancy category C<sup>9</sup></p> <p><b>Nursing:</b> Transfer of naltrexone and 6S-naltrexol into human milk has been reported with oral naltrexone. Because animal studies have shown that naltrexone has a potential for tumorigenicity and other serious adverse reactions in nursing infants, an individualized treatment decision should be made whether a nursing mother will need to discontinue breastfeeding or discontinue naltrexone.</p>	<p><b>Pregnancy:</b> FDA pregnancy category C<sup>9</sup></p> <p>Methadone has been used during pregnancy to promote healthy pregnancy outcomes for more than 40 years. Neonatal abstinence syndrome may occur in newborn infants of mothers who received medication-assisted treatment with methadone during pregnancy. No lasting harm to the fetus has been recognized as a result of this therapy but individualized treatment decisions balancing the risk and benefits of therapy should be made with each pregnant patient.</p> <p><b>Nursing:</b> Mothers maintained on methadone can breastfeed if they are not HIV positive, are not abusing substances, and do not have a disease or infection in which breastfeeding is otherwise contraindicated.</p>	<p><b>Pregnancy:</b> FDA pregnancy category C<sup>9</sup></p> <p>Neonatal abstinence syndrome may occur in newborn infants of mothers who received medication-assisted treatment with buprenorphine during pregnancy. No lasting harm to the fetus has been recognized as a result of this therapy but individualized treatment decisions balancing the risk and benefits of therapy should be made with each pregnant patient.</p> <p><b>Nursing:</b> Buprenorphine and its metabolite norbuprenorphine are present in low levels in human milk and infant urine. Available data are limited but have not shown adverse reactions in breastfed infants.</p>

## ► Potential for Abuse and Diversion

Extended Release Injectable Naltrexone	Methadone	Buprenorphine
No	Yes	Yes

<sup>9</sup>Animal studies have shown an adverse effect on the fetus and there are no adequate, well-controlled studies in humans, but potential benefits may warrant use of the drug in some pregnant women despite potential risks.

### Clinical Opiate Withdrawal Scale

This tool can be used in both inpatient and outpatient settings to reproducibly rate common signs and symptoms of opiate withdrawal and monitor these symptoms over time.

Resting Pulse Rate: \_\_\_\_\_ beats/minute

Measured after patient is sitting or lying for one minute.

- 0 pulse rate 90 or below
- 1 pulse rate 91-100
- 2 pulse rate 101-120
- 4 pulse rate greater than 120

Sweating: Over past 1/2 hour not accounted for by room temperature or patient activity.

- 0 no report of chills or flushing
- 1 subjective report of chills or flushing
- 2 flushed or observable moistness on face
- 3 beads of sweat on brow or face
- 4 sweat streaming off face

Restlessness: Observation during assessment

- 0 able to sit still
- 1 reports difficulty sitting still, but is able to do so
- 2 frequent shifting or extraneous movements of legs/arms
- 3 unable to sit still for more than a few seconds

GI (Gastrointestinal) Upset: Over last 1/2 hour.

- 0 no GI symptoms
- 1 stomach cramps
- 2 nausea or loose stool
- 3 vomiting or diarrhea
- 5 multiple episodes of diarrhea or vomiting

Tremor: Observation of outstretched hands.

- 0 no tremor
- 1 tremor can be felt, but not observed
- 2 slight tremor observable
- 4 gross tremor or muscle twitching

Yawning: Observation during assessment.

- 0 no yawning
- 1 yawning once or twice during assessment
- 2 yawning three or more times during assessment
- 4 yawning several times/minute

Pupil Size:

- 0 pupils pinned or normal size for room light
- 1 pupils possibly larger than normal for room light
- 2 pupils moderately dilated
- 5 pupils so dilated that only the rim of the iris is visible

Bone or Joint Aches: If patient was having pain previously, only the additional component attributed to opiate withdrawal is scored.

- 0 not present
- 1 mild diffuse discomfort
- 2 patient reports severe diffuse aching of joints/muscles
- 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort

Runny Nose or Tearing: Not accounted for by cold symptoms or allergies.

- 0 not present
- 1 nasal stuffiness or unusually moist eyes
- 2 nose running or tearing
- 4 nose constantly running or tears streaming down cheeks

Anxiety or Irritability:

- 0 none
- 1 patient reports increasing irritability or anxiousness
- 2 patient obviously irritable or anxious
- 4 patient so irritable or anxious that participation in the assessment is difficult

Gooseflesh Skin:

- 0 skin is smooth
- 3 piloerection of skin can be felt or hairs standing upon arms
- 5 prominent piloerection

**TOTAL SCORE:** \_\_\_\_\_

The total score is the sum of all 17 items.

► **SCORES:** 0-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

Initials of person completing assessment: \_\_\_\_\_

<http://www.drugabuse.gov/files/fda/med/Res/ClinicalOpiateWithdrawalScale.pdf>

Source: Hesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). *J Psychoactive Drugs*, 35(3), 263-9.

**Disclaimer**

Nothing in this document constitutes an indirect or direct endorsement by the Substance Abuse and Mental Health Services Administration (SAMHSA) or the U.S. Department of Health and Human Services (HHS) of any non-federal entity's products, services, or policies and any reference to a non-federal entity's products, services, or policies should not be construed as such. No official support of or endorsement by SAMHSA or HHS for the opinions, resources, and medications described is intended to be or should be inferred. The information presented in this document should not be considered medical advice and is not a substitute for individualized patient or client care and treatment decisions.

**Electronic Access and Printed Copies**

This publication may be downloaded or ordered at [store.samhsa.gov](http://store.samhsa.gov). Or call SAMHSA at 1-877-SAMHSA-7 (1-877-726-4727) (English and Español).

Information contained in this guide is condensed from the SAMHSA publication *Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide* (SMA14-4892R), which is available at <http://store.samhsa.gov>.

For more information visit:  
<http://www.samhsa.gov>

SMA16-4892PG



Substance Abuse and Mental Health Services Administration. (2016a). *Medication-assisted treatment of opioid use disorder: Pocket guide*. Retrieved from <http://store.samhsa.gov/product/Medication-Assisted-Treatment-of-Opioid-Use-Disorder-Pocket-Guide/SMA16-4892PG>

## Appendix J

### Clinical Opiate Withdrawal Scale

#### Clinical Opiate Withdrawal Scale

For each item, circle the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name: _____ Date and Time ____/____/____:_____	
Reason for this assessment: _____	
<b>Resting Pulse Rate:</b> _____beats/minute Measured after patient is sitting or lying for one minute 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120	<b>GI Upset:</b> over last ½ hour 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting
<b>Sweating:</b> over past ½ hour not accounted for by room temperature or patient activity. 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	<b>Tremor</b> observation of outstretched hands 0 No tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
<b>Restlessness</b> Observation during assessment 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 Unable to sit still for more than a few seconds	<b>Yawning</b> Observation during assessment 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
<b>Pupil size</b> 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	<b>Anxiety or Irritability</b> 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable anxious 4 patient so irritable or anxious that participation in the assessment is difficult
<b>Bone or Joint aches</b> If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	<b>Gooseflesh skin</b> 0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection
<b>Runny nose or tearing</b> Not accounted for by cold symptoms or allergies 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	Total Score _____ The total score is the sum of all 11 items Initials of person completing Assessment: _____

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

From: Wesson DR, Ling W J Psychoactive Drugs 2003 Apr-June; 35(2): 253-9

Wesson, D. R., & Ling, W. (2003). The clinical opiate withdrawal scale (COWS). Journal of Psychoactive Drugs, 35(2), 253. doi:10.1080/02791072.2003.10400007

## Appendix K

## Clinical Institute Withdrawal Assessment of Alcohol Scale-Revised

## Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised (CIWA-Ar)

Patient: _____ Date: _____ Time: _____ (24 hour clock, midnight = 00:00)	
Pulse or heart rate, taken for one minute: _____ Blood pressure: _____	
<b>NAUSEA AND VOMITING</b> -- Ask "Do you feel sick to your stomach? Have you vomited?" Observation. 0 no nausea and no vomiting 1 mild nausea with no vomiting 2 3 4 intermittent nausea with dry heaves 5 6 7 constant nausea, frequent dry heaves and vomiting	<b>TACTILE DISTURBANCES</b> -- Ask "Have you any itching, pins and needles sensations, any burning, any numbness, or do you feel bugs crawling on or under your skin?" Observation. 0 none 1 very mild itching, pins and needles, burning or numbness 2 mild itching, pins and needles, burning or numbness 3 moderate itching, pins and needles, burning or numbness 4 moderately severe hallucinations 5 severe hallucinations 6 extremely severe hallucinations 7 continuous hallucinations
<b>TREMOR</b> -- Arms extended and fingers spread apart. Observation. 0 no tremor 1 not visible, but can be felt fingertip to fingertip 2 3 4 moderate, with patient's arms extended 5 6 7 severe, even with arms not extended	<b>AUDITORY DISTURBANCES</b> -- Ask "Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?" Observation. 0 not present 1 very mild harshness or ability to frighten 2 mild harshness or ability to frighten 3 moderate harshness or ability to frighten 4 moderately severe hallucinations 5 severe hallucinations 6 extremely severe hallucinations 7 continuous hallucinations
<b>PAROXYSMAL SWEATS</b> -- Observation. 0 no sweat visible 1 barely perceptible sweating, palms moist 2 3 4 beads of sweat obvious on forehead 5 6 7 drenching sweats	<b>VISUAL DISTURBANCES</b> -- Ask "Does the light appear to be too bright? Is its color different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?" Observation. 0 not present 1 very mild sensitivity 2 mild sensitivity 3 moderate sensitivity 4 moderately severe hallucinations 5 severe hallucinations 6 extremely severe hallucinations 7 continuous hallucinations
<b>ANXIETY</b> -- Ask "Do you feel nervous?" Observation. 0 no anxiety, at ease 1 mild anxious 2 3 4 moderately anxious, or guarded, so anxiety is inferred 5 6 7 equivalent to acute panic states as seen in severe delirium or acute schizophrenic reactions	<b>HEADACHE, FULLNESS IN HEAD</b> -- Ask "Does your head feel different? Does it feel like there is a band around your head?" Do not rate for dizziness or lightheadedness. Otherwise, rate severity. 0 not present 1 very mild 2 mild 3 moderate 4 moderately severe 5 severe 6 very severe 7 extremely severe
<b>AGITATION</b> -- Observation. 0 normal activity 1 somewhat more than normal activity 2 3 4 moderately fidgety and restless 5 6 7 paces back and forth during most of the interview, or constantly thrashes about	<b>ORIENTATION AND CLOUDING OF SENSORIUM</b> -- Ask "What day is this? Where are you? Who am I?" 0 oriented and can do serial additions 1 cannot do serial additions or is uncertain about date 2 disoriented for date by no more than 2 calendar days 3 disoriented for date by more than 2 calendar days 4 disoriented for place/or person
Total CIWA-Ar Score _____ Rater's Initials _____ Maximum Possible Score 67	

The CIWA-Ar is not copyrighted and may be reproduced freely. This assessment for monitoring withdrawal symptoms requires approximately 5 minutes to administer. The maximum score is 67 (see instrument). Patients scoring less than 10 do not usually need additional medication for withdrawal.

Sullivan, J.T., Sykora, K., Schneiderman, J., Naranjo, C.A., & Sellers, E.M. (1989). Assessment of alcohol withdrawal: The revised Clinical Institute Withdrawal Assessment for Alcohol scale (CIWA-Ar). *British Journal of Addiction* 84:1353-1357.